

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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FRANK MICHOLLE, Individually and on	:	Civil Action No. 1:17-cv-00210-VSB
Behalf of All Others Similarly Situated,	:	(Consolidated)
	:	
Plaintiff,	:	<u>CLASS ACTION</u>
	:	
vs.	:	
	:	
OPHTHOTECH CORPORATION, DAVID R.	:	
GUYER and SAMIR PATEL,	:	
	:	
Defendants.	:	
_____	X	

CONSOLIDATED AMENDED COMPLAINT FOR
VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Lead Plaintiff Sheet Metal Workers' Pension Plan of Southern California, Arizona, and Nevada ("Lead Plaintiff" or "Plaintiff"), by its undersigned attorneys, makes the allegations set forth herein based upon knowledge as to its own acts and upon the investigation conducted by Plaintiff's counsel. That investigation included the examination and analysis of information obtained from public and proprietary sources – including, *inter alia*, United States Securities and Exchange Commission ("SEC") filings by Ophthotech Corporation ("Ophthotech" or the "Company"), regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company, media reports about the Company, and consultations with experts. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of purchasers of the common stock of Ophthotech between March 2, 2015 and December 12, 2016, inclusive (the "Class Period"), seeking to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

2. Defendant Ophthotech is a clinical-stage biopharmaceutical company focused on developing therapies for age-related macular degeneration ("AMD"). The Company's most advanced product candidate during the Class Period was Fovista, an anti-platelet derived growth factor ("anti-PDGF") agent designed to treat a type of AMD known as wet AMD. Wet AMD is a disorder of the central portion of the retina, which is responsible for central vision and color perception. Wet AMD patients experience symptoms such as blurred vision and blind spots in their visual field caused by abnormal blood vessels that leak fluid or blood into the retina.

3. Fovista was designed to block proteins that bind to cells on the *outer*¹ lining of the abnormal blood vessels associated with wet AMD. Fovista was to be administered in combination with anti-vascular endothelial growth factor (“anti-VEGF”) agents, which represent the current standard of care for the treatment of wet AMD. Anti-VEGF agents block proteins that bind to cells on the *inner* lining of blood vessels. In theory, by combining an anti-PDGF agent like Fovista with an anti-VEGF agent, proteins on both the inner and outer lining of the abnormal blood vessels would be blocked, more effectively promoting blood vessel regression and reducing leakage and scarring.

4. In June 2012, Ophthotech completed a Phase 2b clinical trial of Fovista in combination with the anti-PDGF drug Lucentis (the “Phase 2b Trial”). The Phase 2b Trial ostensibly demonstrated “extraordinary,” “breakthrough” results for Fovista, including a “62% additional benefit” to patients’ visual acuity from treatment with Fovista in combination with Lucentis, compared to Lucentis alone. Following the Phase 2b Trial, Ophthotech went public and raised hundreds of millions of dollars to fund its Phase 3 clinical program, designed to support regulatory approval of Fovista (the “Phase 3 Trials”).

5. Throughout the Class Period, Defendants repeatedly highlighted the “*statistical and clinical significance*” of the Phase 2b Trial’s results, including the “*62% additional benefit* over monotherapy,” and characterized the trial as “well conducted” and its “data” as “robust.” In truth, the Phase 2b Trial was not indicative of Fovista’s efficacy because, unbeknownst to investors, the results of the trial were skewed by the fact that patients in the Lucentis-only group had larger lesions² and poorer vision at the start of the trial than patients in the Fovista combination group. As

¹ All emphasis is added unless otherwise noted.

² In wet AMD patients, areas of abnormal blood vessels and altered tissue are referred to as lesions. The lesions present in wet AMD patients are typically categorized by “classic” and “occult” subtypes.

a result, patients in the Lucentis-only group were less likely to experience an improvement in visual acuity during the trial than patients in the Fovista combination group because their symptoms were more chronic, severe and difficult to treat. Therefore, the comparative improvement in visual acuity experienced by patients in the Fovista combination group was not necessarily attributable to Fovista, but rather, was due to the fact that patients with less severe symptoms were more likely to respond to standard of care anti-VEGF therapy.

6. Defendants also emphasized that they had “made *no meaningful changes* to the inclusion and exclusion criteria in the[] Phase 3 clinical trials from those [] used in [the] Phase 2b clinical trial” – when in fact, they had made a significant change. Whereas the Phase 2b Trial had categorized patients by lesion subtype and excluded patients with a subtype known as “pure occult” lesions, the enrollment criteria for the Phase 3 Trials were based upon the presence of subretinal hyper-reflective material (“SHRM”) – a type of abnormal tissue observable in some wet AMD patients.

7. Although SHRM was a newly-discovered phenomenon that had not been thoroughly studied and was not fully understood, Defendants represented that SHRM was “the same as” the “classic” lesion subtype, insisted that “the same group of patients” was eligible for inclusion in the Phase 3 Trials as in the Phase 2b Trial, and denied that patients with occult lesions were eligible for inclusion in the Phase 3 Trials.

8. In fact, SHRM can be present in patients with either classic or occult lesion subtypes. Therefore, this change to the enrollment criteria was dramatic because it meant that the estimated 40% of wet AMD patients with pure occult lesions – who had been excluded from the Phase 2b Trial – were now eligible for inclusion in the Phase 3 Trials. By making a significant change to the enrollment criteria for the Phase 3 Trials from the criteria used in the Phase 2b Trial, Defendants

materially increased the risk that the apparently favorable results of the Phase 2b Trial would not be replicated in the Phase 3 Trials.

9. Defendants similarly misrepresented that they had only “modified the *methodology* used to determine a patient’s eligibility” for the Phase 3 Trials by utilizing a new imaging technology that would enable Ophthotech to “properly classify [lesion] characteristics . . . in an accurate and standardized manner prior to enrolling [patients] in the [Phase 3] trials” – when in fact, they had modified the *enrollment criteria* by requiring only the presence of SHRM.

10. Given the seemingly “extraordinary” results of the Phase 2b Trial, and the purported similarity of the Phase 3 Trials to the Phase 2b Trial, analysts and investors were highly optimistic about the likelihood that the Phase 3 Trials would yield favorable results and set the stage for regulatory approval of Fovista. By contrast, knowing that Fovista’s prospects for success were much riskier than they had disclosed, Ophthotech’s two co-founders, Defendants David R. Guyer, M.D. (“Guyer”) and Samir C. Patel, M.D. (“Patel”), *both sold the majority* of their personally-held Ophthotech stock, with Guyer selling **66.3%** of his shares for proceeds of approximately **\$22.6 million**, and Patel selling **82.2%** of his shares for proceeds of approximately **\$22.9 million** – ensuring that they would become wealthy even if Fovista failed.

11. On December 12, 2016, Ophthotech stunned investors by announcing the results of the Phase 3 Trials and disclosing that “[*n*]o benefit [*was*] observed upon [the] addition of Fovista® to monthly Lucentis® regimen for the treatment of wet [AMD.]” In response to this news, the price of Ophthotech common stock plummeted **86%** on more than 30 times the previous day’s trading volume.

12. Analysts and investors expressed surprise and confusion at the complete failure of Fovista, with one analyst summarizing the situation as follows: “[W]e considered the potential

causes for concern,” including Ophthotech “management significantly reducing their ownership stake ahead of results[], but ultimately we chose to believe that these elements could be explained away in the face of what looked like impressive Phase II results. Rather than being red herrings, these were red flags Fovista simply doesn’t work.”

13. Ophthotech subsequently abandoned its Fovista clinical program, and the Company’s common stock currently trades well below \$3.00 per share – a dramatic decline from the stock’s Class Period high of \$78.64 per share.

JURISDICTION AND VENUE

14. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder by the SEC [17 C.F.R. §240.10b-5].

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and Section 27 of the Exchange Act [15 U.S.C. §78aa].

16. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. §1391(b). Ophthotech is headquartered in this District and many of the acts that constitute the alleged violations of law occurred in this District.

17. In connection with the acts alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

18. Lead Plaintiff Sheet Metal Workers’ Pension Plan of Southern California, Arizona, and Nevada purchased Ophthotech common stock during the Class Period, as set forth in the certification previously filed with the Court and incorporated herein by reference, and has been damaged thereby.

19. Defendant Ophthotech was founded in 2007 by Defendants Guyer and Patel. Ophthotech's principal executive offices are located at One Penn Plaza, 35th Floor, New York, New York 10119. The Company's common stock is listed and trades on the NASDAQ, an efficient market, under the ticker symbol "OPHT."

20. Defendant Guyer is a co-founder of Ophthotech and was, at all relevant times, the Company's Chief Executive Officer ("CEO") and Chairman of the Board of Directors. During the Class Period, Defendant Guyer was responsible for directing Ophthotech's corporate and financial strategy.

21. Defendant Patel is a co-founder of Ophthotech and was, at all relevant times, the Company's President and Vice Chairman of the Board of Directors. During the Class Period, Defendant Patel was responsible for the clinical development of Fovista.

22. Defendants Guyer and Patel are collectively referred to herein as the "Individual Defendants." Ophthotech and the Individual Defendants are collectively referred to herein as "Defendants."

23. During the Class Period, the Individual Defendants, as senior executive officers and/or directors of Ophthotech, were privy to confidential and proprietary information concerning Ophthotech and its operations, finances, financial condition, and present and future business prospects. As discussed below, the Individual Defendants had access to material, adverse, non-public information concerning Ophthotech via internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and/or board of directors meetings and committees thereof, and via reports and other information provided to them in connection therewith. Because of their possession of such information, the Individual Defendants

knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

24. The Individual Defendants are liable as direct participants in the wrongs complained of herein. In addition, the Individual Defendants, by reason of their status as senior executive officers and/or directors, were “controlling persons” within the meaning of Section 20(a) of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to and did, directly or indirectly, control the conduct of Ophthotech’s business.

25. The Individual Defendants, because of their positions with the Company, controlled and/or possessed the authority to control the contents of its reports, press releases and presentations to securities analysts and through them, to the investing public. The Individual Defendants were provided with copies of the Company’s reports and press releases alleged herein to be misleading, prior to or shortly after their issuance, and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, the Individual Defendants had the opportunity to commit the fraudulent acts alleged herein.

26. As senior executive officers and/or directors and as controlling persons of a publicly traded company whose common stock was registered with the SEC pursuant to the Exchange Act, and was traded on the NASDAQ and governed by the federal securities laws, the Individual Defendants had a duty to promptly disseminate accurate and truthful information with respect to Ophthotech’s financial condition and performance, growth, operations, business, products, markets, management, earnings and present and future business prospects, and to correct any previously issued statements that had become materially misleading or untrue, so that the market price of Ophthotech common stock would be based upon truthful and accurate information. The Individual

Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

27. Each Defendant is liable as a participant in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of Ophthotech common stock by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived the investing public regarding Ophthotech's business and prospects and the intrinsic value of Ophthotech common stock; (ii) enabled the Individual Defendants to collectively sell over \$45 million worth of Ophthotech common stock to the unsuspecting public at artificially inflated prices at times and in amounts that were unusual; and (iii) caused Lead Plaintiff and other members of the Class (defined below) to purchase Ophthotech common stock at artificially inflated prices.

SUBSTANTIVE ALLEGATIONS

The Company and Its Business

28. Defendant Ophthotech is a clinical-stage biopharmaceutical company focused on developing therapies for AMD.

29. Throughout the Class Period, Ophthotech concentrated its efforts on the development of its most advanced product candidate, Fovista, designed to treat wet AMD. Wet AMD occurs when abnormal blood vessels form and invade the retina – a process known as choroidal neovascularization ("CNV"). The abnormal blood vessels leak fluid or blood into the macula, the portion of the retina responsible for central vision and color perception.

30. Wet AMD distorts the vision necessary for daily activities such as reading, face recognition and driving, and is the leading cause of blindness in people over the age of 55 in the United States and Europe. Wet AMD represents approximately 10% of all cases of AMD, but is responsible for 90% of the severe vision loss associated with the disease. There is currently no cure for wet AMD and approved treatments focus on slowing its progression.

31. During the Class Period, Fovista was in clinical development for use in combination with anti-VEGF drugs that represent the current standard of care for the treatment of wet AMD. Anti-VEGF drugs block proteins that bind to cells on the inner lining of the abnormal blood vessels associated with wet AMD, inhibiting cell proliferation. By contrast, Fovista, as an anti-PDGF agent, was designed to block proteins that bind to cells on the outer lining of the abnormal blood vessels, disrupting cell survival signals. In theory, by combining an anti-PDGF agent like Fovista with an anti-VEGF agent, proteins on both the inner and outer lining of the abnormal blood vessels would be blocked, promoting blood vessel regression and inhibiting scarring (known as fibrosis), more effectively than anti-VEGF monotherapy.

The Phase 2b Trial of Fovista in Combination with Lucentis

32. Prior to the start of the Class Period, Ophthotech had completed phase 1 and phase 2 clinical trials evaluating Fovista in combination with the approved anti-VEGF drug Lucentis, and had initiated phase 3 clinical trials.³

33. Ophthotech's Phase 2b Trial was designed to evaluate the safety and efficacy of two different doses of Fovista administered in combination with Lucentis, compared to Lucentis monotherapy. The Phase 2b Trial was a 24-week, randomized, double-masked clinical trial of 449 patients with wet AMD.

³ In order to secure approval by the U.S. Food and Drug Administration ("FDA"), a new drug must typically succeed in three phases of clinical trials. Phase 1 trials involve the initial introduction of the drug into a small group of patients with the target disease to assess how the drug is metabolized, the drug's safety profile, and the safe dosage range. Phase 2 trials are designed to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug, and to assess dosage tolerance and optimal dosage on a medium-sized group of patients. Phase 2 trials are sometimes sub-divided, with phase 2a focused on assessing safety and phase 2b focused on assessing clinical efficacy and dosage. Phase 3 trials expand the safety and efficacy assessment to a larger group of patients, and are designed to generate enough data to statistically evaluate the drug for potential approval, to establish the overall benefit-risk relationship of the drug, and to provide adequate information for the labeling of the drug.

34. The “primary efficacy endpoint” (*i.e.*, the main, pre-determined objective) of the trial was the mean change in visual acuity from baseline at 24 weeks for Fovista and Lucentis combination therapy, compared to Lucentis monotherapy. Visual acuity was measured by the number of letters, arranged in lines, that a patient could read on the Early Treatment Diabetic Retinopathy Study (“ETDRS”) eye chart, a standardized chart used for vision testing. Prior to the start of the trial, each patient’s visual acuity was measured to establish a baseline. Patients were then randomly assigned to one of three treatment groups, and were treated and assessed once every four weeks for 24 weeks.

35. During the trial: (1) the first group of patients received injections of 1.5 mg of Fovista following injections of 0.5 mg of Lucentis; (2) the second group of patients received injections of 0.3 mg of Fovista following injections of 0.5 mg of Lucentis; and (3) the control group of patients received sham injections following injections of 0.5 mg of Lucentis.

36. On June 13, 2012, Ophthotech – then a privately held company – issued a press release announcing purportedly blockbuster results from the Phase 2b Trial. According to the press release, the Phase 2b Trial showed “*statistically significant superior efficacy over Lucentis . . . monotherapy* for the treatment of . . . [wet AMD].” The press release stated, in pertinent part, as follows:

In a prospective, randomized, controlled Phase 2b clinical trial of 449 patients with wet AMD, Ophthotech’s Fovista[] anti-PDGF therapy (1.5 mg), administered in combination with Lucentis anti-VEGF therapy, met the pre-specified primary efficacy endpoint of mean vision gain. **Patients receiving the combination of Fovista (1.5 mg) and Lucentis gained a mean of 10.6 letters of vision on the ETDRS standardized chart at 24 weeks, compared to 6.5 letters for patients receiving Lucentis monotherapy (p=0.019), representing a 62% additional benefit.** No significant safety issues were observed for either treatment group in the trial.

Enhanced visual outcomes of Fovista anti-PDGF (1.5 mg) combination therapy as compared to Lucentis monotherapy were demonstrated at every monthly timepoint. In addition, the relative magnitude of visual benefit continued to

increase over time. The visual benefit of anti-PDGF (1.5 mg) combination therapy compared to Lucentis monotherapy was greater at the 6-month timepoint than at the 3-month timepoint. **The increasing divergence of the efficacy curves suggests the benefit of chronic anti-PDGF combination therapy. A classic dose-response curve was observed.**

“This is a truly remarkable finding for patients with wet AMD. To achieve a 62% relative visual benefit over anti-VEGF monotherapy is extraordinary,” commented retina specialist Carmen A. Puliafito, M.D., Dean of the Keck School of Medicine at the University of Southern California.⁴ *“The very compelling and robust results of this well-executed study validate PDGF as an important target for wet AMD and set the stage for a new era of combination therapy via co-formulation or fixed-combination delivery. I look forward to the rapid development of this important drug for our patients.”*

The robust benefit of Fovista anti-PDGF (1.5 mg) combination therapy over Lucentis monotherapy was consistent across all subgroups including those analyzing baseline vision, lesion size and the proportion of patients gaining 1, 2, 3, 4 and 5 lines of vision (ETDRS standardized chart). An average absolute benefit of 7.4% over Lucentis monotherapy was present across all ETDRS lines of vision gain. In addition, a relative benefit of 25% over Lucentis monotherapy was attained in patients who gained 3 or more lines of vision, with 69% and 178% relative benefit in patients gaining 4 or more and 5 or more lines of vision, respectively.

Donald J. D’Amico, M.D., Professor and Chairman of Ophthalmology at the Weill Cornell Medical College, added, *“This breakthrough study is a major step forward in our treatment of patients with wet AMD and represents a clear paradigm shift. This convincing study shows clinically significant improvements in visual outcomes in all patient subgroups over six months. In addition to delivering the promise of enhanced visual gain, I am delighted with the potential of pairing this anti-PDGF entity with any of the increasing number of anti-VEGF agents in the marketplace.”*

Defendant Patel commented, in pertinent part, as follows:

We are very encouraged by the strong and consistent enhanced efficacy demonstrated in this large trial. Based on these results, Ophthotech plans to expedite the preparation of a Phase 3 registration program with the goal of bringing Fovista anti-PDGF therapy to patients with wet AMD as soon as possible.

(Italics in original.)

⁴ Dr. Puliafito is a former classmate and long-standing acquaintance of Defendants Guyer and Patel.

37. Accordingly, the Phase 2b Trial purportedly demonstrated that Fovista in combination with Lucentis was 62% more effective than Lucentis alone in producing visual acuity gain. More specifically, the Fovista combination group improved an average of 10.6 letters after 24 weeks, as opposed to the Lucentis monotherapy group, which improved an average of 6.5 letters after 24 weeks.

38. On the heels of the Phase 2b Trial's seemingly "extraordinary" results, Ophthotech embarked on a massive fundraising spree.

39. On May 29, 2013, Ophthotech announced that it had raised \$175 million to finance its Phase 3 Trials of Fovista from Novo A/S, an international venture capital firm. Of that amount, Ophthotech received \$125 million from Novo A/S in exchange for royalties on Fovista sales. The remaining \$50 million consisted of a Series C preferred stock financing from Novo A/S and venture investors in Ophthotech.

40. On September 30, 2013, Ophthotech completed its initial public offering ("IPO"), whereby the Company sold 8,740,000 shares of its common stock to the public at \$22.00 per share. The IPO generated net proceeds of approximately \$175.6 million.

41. Shortly thereafter, on February 18, 2014, Ophthotech completed a secondary public offering, whereby 2,628,571 shares of its common stock were sold to the public at \$31.50 per share, generating net proceeds of approximately \$55.4 million.

42. Finally, on May 19, 2014, Ophthotech entered into an agreement with Novartis Pharma AG ("Novartis"). Among other terms, Ophthotech received a \$200 million upfront payment from Novartis, and was eligible to receive payments of up to \$130 million upon achieving certain enrollment milestones in the Phase 3 Trials. In return, Ophthotech granted Novartis exclusive rights to commercialize Fovista in markets outside of the United States.

The Fovista Phase 3 Trials

43. One month before the IPO, on August 29, 2013, Ophthotech launched its “pivotal” phase 3 clinical program, aimed at securing approval of Fovista by the FDA and other regulatory agencies worldwide.

44. The phase 3 program consisted of three separate randomized, double-masked clinical trials designed to evaluate the safety and efficacy of Fovista administered in combination with anti-VEGF drugs for the treatment of wet AMD, compared to anti-VEGF monotherapy. The first two trials, like the Phase 2b Trial, evaluated Fovista in combination with Lucentis (the “Fovista Phase 3 Lucentis Trials”), and the third trial evaluated Fovista in combination with anti-VEGF drugs Eylea or Avastin (the “Fovista Phase 3 Eylea/Avastin Trial”).

45. As in the Phase 2b Trial, the primary efficacy endpoint in each of the Phase 3 Trials was the mean change in visual acuity (measured by the ETDRS eye chart) from baseline for Fovista and anti-VEGF combination therapy, compared to anti-VEGF monotherapy. In the Phase 3 Trials however, the mean change in visual acuity was measured at 12 months, as opposed to the 24-week time period used in the Phase 2b Trial.

46. In the Fovista Phase 3 Lucentis Trials, patients were randomly assigned to one of two treatment groups and were treated and assessed monthly. The first group of patients in each trial received injections of 1.5 mg of Fovista following injections of 0.5 mg of Lucentis. The second group of patients in each trial, who served as the control groups, received sham injections following injections of 0.5 mg of Lucentis. Because the two Fovista Phase 3 Lucentis Trials shared an identical design during the first 12 months, the databases from both trials were to be “locked” until

the primary endpoints of both trials were completed, at which time they would be unmasked and analyzed together.⁵

47. In the Fovista Phase 3 Eylea/Avastin Trial, patients were likewise randomly assigned to two treatment groups and treated and assessed monthly. The first patient group was further divided in half and received either: (1) 1.5 mg of Fovista following injections of 1.25 mg of Avastin; or (2) 1.5 mg of Fovista following injections of 2.0 mg of Eylea. The second patient group, which served as the control group, was likewise divided in half and received either: (1) sham injections following injections of 1.25 mg of Avastin; or (2) sham injections following injections of 2.0 mg of Eylea. The patients who received Avastin were treated monthly for 24 months and the patients who received Eylea were treated every month for the first three months followed by every other month thereafter.

48. 1,891 patients were enrolled in the Phase 3 Trials at approximately 250 centers internationally. The Company completed enrollment in the two Fovista Phase 3 Lucentis Trials in May 2015 and November 2015, respectively, and planned to announce initial, top-line data from both trials during the fourth quarter of 2016. The Company completed enrollment in the Fovista Phase 3 Eylea/Avastin Trial in June 2016 and planned to announce initial-top-line data from the trial during the second half of 2017.

49. During the Class Period, investors were singularly focused on the likelihood that the Phase 3 Trials would succeed. The success of the Phase 3 Trials was a necessary precursor to securing FDA approval of Fovista, so that Ophthotech could commercialize the drug and eventually become a profitable company.

⁵ In the first Fovista Phase 3 Lucentis Trial, during the second 12 months, patients were to be treated every other month and could be re-treated during the intervening months in accordance with specific retreatment criteria. In the second Fovista Phase 3 Lucentis Trial, during the second 12 months, treatment was to be administered based upon the stability of the patient's visual acuity.

The Results of the Phase 2b Trial Were Not Indicative of Fovista's Efficacy Because They Were Skewed by Imbalances in Patient Characteristics

50. During the Class Period, Defendants continuously highlighted the results of the Phase 2b Trial, including the Fovista group's "62% comparative benefit from baseline," the "statistical and clinical significance" of patients' mean change in visual acuity, and the "classic dose response curve with an early and sustained improvement." Unbeknownst to investors, however, the Phase 2b Trial was not indicative of Fovista's efficacy because the results of the trial were skewed by imbalances in patients' baseline characteristics between the control and therapy arms of the trial.

51. Specifically, in the Lucentis-only group, the mean total lesion size among patients' study eyes was 1.8 disc areas – approximately 17% larger than the 1.5 disc area mean total lesion size among patients in the Fovista combination group.⁶ This was significant because larger lesions tend to be more chronic, severe and difficult to treat. Since patients receiving Fovista had smaller lesions to begin with, their vision was more likely to improve with standard of care anti-VEGF therapy – and that improvement was not necessarily attributable to the addition of Fovista.

52. Moreover, it is likely that patients in the Lucentis-only group, on average, had poorer visual acuity at baseline than patients in the Fovista combination group, since larger lesions correlate with poorer visual acuity. This additional imbalance likewise skewed the results of the trial, since patients with poorer vision are less likely to respond to treatment.

Defendants Made a Significant Change to Patient Enrollment Criteria in the Phase 3 Trials

53. In addition, despite representing to investors that Ophthotech had "*made no meaningful changes* to the inclusion and exclusion criteria in the[] Phase 3 clinical trials from those [] used in [the] Phase 2b clinical trial," in truth, Defendants made a critical change.

⁶ Lesion size is measured in units called "disc area." A disc area is the size of the area of the retina where a standard sized optic nerve emerges.

54. Ophthotech's Phase 2b Trial had excluded patients with a particular type of lesion, called "pure occult" lesions. Wet AMD patients are typically divided into subtypes based upon the type of lesions that are present. Lesions are made up of "classic" and "occult" components. Classic refers to the portion of the lesion that is well-defined and typically located above the "RPE" layer of the retina.⁷ Occult refers to the portion of the lesion that is poorly defined and typically located below the RPE layer of the retina. Classic and occult subtypes represent a spectrum, with "pure classic" lesions containing no occult components, and "pure occult" lesions containing no classic components. Between these extremes, "predominantly classic" lesions contain 50% or greater classic components, and "minimally classic" lesions contain less than 50% classic components. The pure occult subtype that was excluded from the Phase 2b Trial accounts for approximately **40%** of wet AMD cases.

55. In the Phase 3 Trials, instead of categorizing patients based upon whether their lesions had classic or occult components, and then excluding patients with pure occult lesions, Ophthotech based its enrollment criteria on the presence of SHRM – a type of abnormal tissue observable in some wet AMD patients.

56. In contrast to classic and occult lesions, SHRM was a newly-discovered phenomenon, and its relationship to visual acuity in wet AMD patients had not been thoroughly studied and was not fully understood. According to Ophthotech, "[t]he presence of [SHRM] is thought by many experts to indicate the presence of [a] CNV lesion. The subsequent resolution of [SHRM] is thought to correlate with regression of the CNV lesion."

57. This change in enrollment criteria was facilitated by advances in retinal imaging technology, whereby fluorescein angiography was being replaced by spectral domain optical

⁷ The RPE layer of the retina lies between the choroid and the neurosensory region of the retina.

coherence tomography (“SD-OCT”) as the standard imaging technology.⁸ While SD-OCT, like fluorescein angiography, was capable of detecting lesion characteristics associated with classic and occult subtypes, the presence of SHRM could only be detected using SD-OCT.

58. Critically, SHRM can be present in patients whose lesions have either classic or occult components – including patients with pure occult lesions. Therefore, this change to the enrollment criteria meant that patients with pure occult lesions – who had been excluded from the Phase 2b Trial – were eligible for inclusion in the Phase 3 Trials.

59. By making a significant change to the enrollment criteria for the Phase 3 Trials from the criteria used in the Phase 2b Trial, Defendants materially increased the risk that the seemingly favorable results of the Phase 2b Trial would not be replicated in the Phase 3 Trials. Defendants, however, failed to adequately disclose this increased risk to investors.

60. Indeed, Defendants knew, or should have known, that the changed enrollment criteria significantly impacted the Phase 3 Trials’ prospects for success, because when images of patients’ lesions were examined at the end of Ophthotech’s phase 1 clinical trial of Fovista, the occult components of the lesions appeared to be unaffected by treatment with Fovista.

MATERIALLY FALSE AND MISLEADING STATEMENTS MADE DURING THE CLASS PERIOD

61. The Class Period begins on March 2, 2015. On that date, Ophthotech filed its annual report for the year ended December 31, 2014 with the SEC on Form 10-K, which was signed by

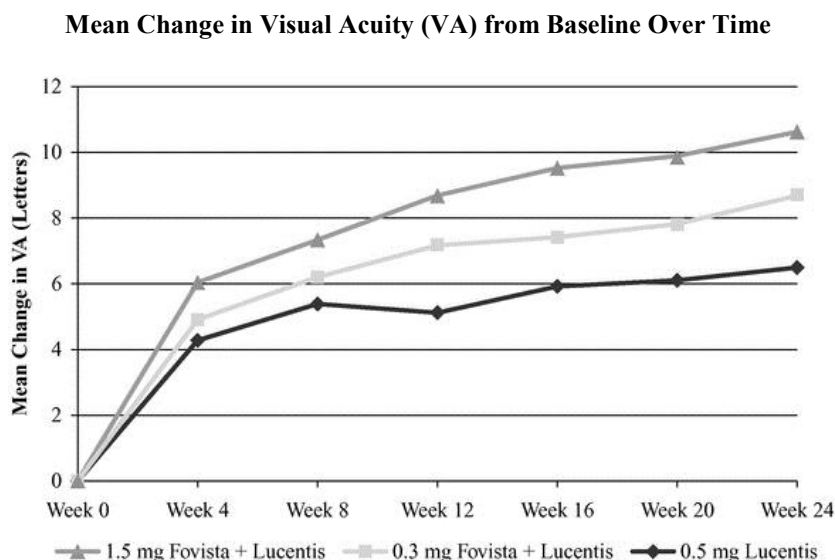
⁸ SD-OCT utilizes scattered light to obtain high-resolution retinal tissue images with a specialized camera. SD-OCT images show a cross-sectional view of the retina that permits enhanced resolution of the space under the retina and the RPE layer. Fluorescein angiography involves injecting a dye and capturing its image during circulation through the retina using a specialized camera. SD-OCT allows for a more precise assessment of anatomical differences between subtypes of CNV lesions, especially with respect to whether neovascularization is located above or below the RPE layer. Fluorescein angiography continues to be used as well, however, because of its high sensitivity in detecting the presence of an active lesion.

Defendants Guyer and Patel. The 2014 Form 10-K highlighted the results of the Phase 2b Trial and its similarity to the ongoing Phase 3 Trials, stating, in pertinent part, as follows:

In our completed Phase 2b clinical trial, the combination of 1.5 mg of Fovista and Lucentis demonstrated statistically significant superiority compared to Lucentis monotherapy based on the primary endpoint of mean change in visual acuity from baseline at 24 weeks, providing a 62% comparative benefit from baseline. Our Phase 3 clinical program builds on and incorporates significant aspects from the design of our Phase 2b clinical trial.

* * *

[T]he following graph sets forth the mean change in visual acuity from baseline for each treatment group in our Phase 2b clinical trial over the course of the trial:



We observed a visual benefit in patients treated with the combination of 1.5 mg of Fovista and Lucentis early in and sustained over the course of treatment. The relative magnitude of visual benefit increased over the study period. We believe that these results suggest that Fovista may provide benefit to patients when used over time in combination with Lucentis.

62. The statements referenced above in ¶61 were materially false and misleading because Defendants knew, or recklessly disregarded, but failed to disclose that the results of the Phase 2b Trial were not indicative of Fovista's efficacy, since those results were skewed by the fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group. In addition, the statement referenced above in ¶61 that "[o]ur Phase

3 clinical program builds on and incorporates significant aspects from the design of our Phase 2b clinical trial” falsely and misleadingly communicated that the Phase 3 Trials were similar in design to the Phase 2b Trial, when in truth, Defendants had made a significant change to the patient enrollment criteria for the Phase 3 Trials. Whereas the Phase 2b Trial had excluded patients with pure occult lesions, by requiring only the presence of SHRM for enrollment in the Phase 3 Trials, Ophthotech was permitting patients with pure occult lesions to be included in the Phase 3 Trials.

63. The 2014 Form 10-K further emphasized the similarity between the Phase 2b and Phase 3 Trials’ design and patient eligibility criteria, stating, in pertinent part, as follows:

While we have modified the methodology used to determine a patient’s eligibility under certain of the inclusion and exclusion criteria for our Phase 3 clinical trials as compared to our Phase 2b clinical trial, we have made no meaningful changes to the inclusion and exclusion criteria in these Phase 3 clinical trials from those we used in our Phase 2b clinical trial. We expect that this will result in the enrollment of a patient population similar to the patient population enrolled in our Phase 2b clinical trial.

* * *

We have made no meaningful changes to the inclusion and exclusion criteria in these Phase 3 clinical trials from those we used in our Phase 2b clinical trial. However, we have modified the methodology used to determine a patient’s eligibility under certain of the inclusion and exclusion criteria for our Phase 3 clinical trials as compared to our Phase 2b clinical trial. We are enrolling patients in our Phase 3 clinical program based on a specific definition of the presence of neovascularization based on diagnostic imaging of the retina. The most commonly employed and standard modality for neovascular AMD imaging in a typical retinal specialty based practice is SD-OCT. Other diagnostic modalities usually employed by many retinal physicians include fluorescein angiogram and fundus photos. ***To ensure that uniform criteria are applied in characterizing patients’ neovascular lesions, we have engaged a centralized reading center to review the SD-OCT, fluorescein angiogram and fundus photos of each patient’s affected eye. The reading center uses these imaging modalities to assess the eligibility of the abnormal new blood vessels at the time of enrollment.***

64. The statements referenced above in ¶63 were materially false and misleading because Defendants knew, or recklessly disregarded, but failed to disclose that Defendants had not merely “modified the ***methodology*** used to determine a patient’s eligibility” in the Phase 3 Trials – they had

modified the enrollment criteria. In truth, Defendants **had** “made [a] meaningful change[] to the inclusion and exclusion criteria in the[] Phase 3 clinical trials from those [] used in [the] Phase 2b clinical trial.” Whereas the Phase 2b Trial had excluded patients with pure occult lesions, by requiring only the presence of SHRM for enrollment in the Phase 3 Trials, Ophthotech was permitting patients with pure occult lesions to be included in the Phase 3 Trials. Likewise, the statement referenced above in ¶63 that “[w]e are enrolling patients in our Phase 3 clinical program based on a specific definition of the presence of neovascularization based on diagnostic imaging of the retina” failed to disclose that enrollment in the Phase 3 Trials required only the presence of SHRM. Because the changed enrollment criteria meant that the estimated 40% of wet AMD patients with pure occult lesions were eligible to participate in the Phase 3 Trials, Defendants had no reasonable basis to “expect that” the Phase 3 Trials would “enroll[] . . . a patient population similar to the patient population enrolled in [the] Phase 2b clinical trial.”

65. In addition, the 2014 Form 10-K contained the following description of the imaging technologies used to detect lesion characteristics:

. . . The process for determining whether or not a wet AMD patient has pure occult choroidal neovascularization has evolved considerably in the United States and European Union over the last five years, with SD-OCT replacing fluorescein angiography as the diagnostic standard. There is significant variability and inconsistency among physicians and reading centers with respect to the determination of the presence and amount of the occult component of lesions using fluorescein angiography. Different reading centers may categorize a patient differently on the basis of the same image if fluorescein angiography is used to assess the occult component of choroidal neovascularization. We believe the use of SD-OCT to assess choroidal neovascularization at the time of enrollment in our Phase 3 clinical trials will alleviate some of the variability and inconsistency inherent in using fluorescein angiography. SD-OCT will be used to assess the characteristics of abnormal new vessels, which historically, using fluorescein angiography, have been associated with the subtype occult neovascularization. SD-OCT is the current standard of imaging of wet AMD patients and we believe that the use of SD-OCT will provide a more precise analysis of the anatomical differences between the various angiographic subtypes of CNV lesions in neovascular AMD.

* * *

We believe that use of . . . the latest imaging technologies enables us to confirm patient eligibility and properly classify neovascular characteristics and the associated leakage in an accurate and standardized manner prior to enrolling them in the trial.

66. The statements referenced above in ¶65 were materially false and misleading because they characterized SD-OCT imaging as a considerable advancement in “[t]he process for determining whether or not a wet AMD patient has pure occult” lesions, which would lead to more accurate categorization of patients by lesion subtype, but failed to disclose that Defendants had made a significant change to the patient enrollment criteria for the Phase 3 Trials with respect to lesion subtypes. Whereas the Phase 2b Trial had excluded patients with pure occult lesions, by requiring only the presence of SHRM for enrollment in the Phase 3 Trials, Ophthotech was permitting patients with pure occult lesions to be included in the Phase 3 Trials.

67. On March 10, 2015, during the Barclays Healthcare Conference, Defendant Guyer highlighted that “*our Phase 2b . . . demonstrated statistically significant superiority* in a large randomized, controlled . . . trial *showing a 62% comparative benefit from baseline over Lucentis standard of care anti-VEGF monotherapy . . .*”

68. Likewise, speaking at the Deutsche Bank Healthcare Conference on May 7, 2017, Defendant Guyer again emphasized that Ophthotech’s “*Phase 2b data demonstrated statistically significant superiority* in . . . the largest Phase 2b ever done in AMD, randomized controlled Phase 2b trial, where we *showed a 62% comparative benefit from baseline over standard of care Lucentis anti-VEGF monotherapy*,” adding that “we found that *classic dose-response curve with continuing divergence*.”

69. The statements referenced above in ¶¶67-68 were materially false and misleading because Defendant Guyer knew, or recklessly disregarded, but failed to disclose that the results of the Phase 2b Trial were not indicative of Fovista’s efficacy, since those results were skewed by the

fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group.

70. On May 11, 2015, Ophthotech issued a press release announcing that the Company had completed patient enrollment in the first Fovista Phase 3 Lucentis Trial. Later that day, Defendants held a conference call with analysts and investors, during which an analyst asked about the enrollment criteria for the Phase 3 Trials, and Defendant Patel responded, in pertinent part, as follows:

Joseph Schwartz – Leerink Partners – Analyst:

. . . I was wondering, first of all, *how are you selecting patients for inclusion into these Phase 3 trials on top of Lucentis? Is it just classic features of wet AMD or is it the presence of SHRM or both?* Which is believed to correlate stronger with anti-PDGF activity?

* * *

Defendant Patel:

So, it's SHRM by OCT

* * *

Obviously when we started the Phase 3, the use of a fluorescein angiogram, as you know, is quite unusual and rare nowadays. Virtually everybody uses OCT and the OCT is very high resolution, and *its sensitivity and specificity has determined the location of the fluorelier vascularization with respect to the RPE, which is what you are really trying to do when you look at classic [and it] is better and more accurate. So it is for that reason we switched over to using SHRM. In essence, the definition for the use of the term classic refers to fluorescein angiogram. [Its] equivalent component on OCT is called SHRM.*

71. The statements referenced above in ¶70 that SHRM was “equivalent” to classic lesions, and that the use of SD-OCT imaging would result in “better and more accurate” categorization of patients by lesion subtype were materially false and misleading because Defendant Patel knew, or recklessly disregarded, but failed to disclose that Defendants had made a significant change to the patient enrollment criteria for the Phase 3 Trials with respect to lesion subtypes.

Whereas the Phase 2b Trial had excluded patients with pure occult lesions, by requiring only the presence of SHRM for enrollment in the Phase 3 Trials, Ophthotech was permitting patients with pure occult lesions to be included in the Phase 3 Trials. In addition, SHRM was not “equivalent” to classic lesions because SHRM may be present in patients whose lesions have either classic or occult components – including patients with pure occult lesions.

72. On May 13, 2015, speaking at the Bank of America Merrill Lynch Healthcare Conference, Defendant Guyer reiterated that “*the Phase 2b trial*, the largest ever done in wet AMD . . . *demonstrated both statistical and clinical significance* in a superiority trial with Lucentis monotherapy, *showing a 62% comparative benefit from baseline against standard of care Lucentis*. . . .”

73. On May 18, 2015, speaking at the UBS Global Healthcare Conference, Defendant Guyer stated that “[O]ur *Phase IIb Wet AMD Fovista trial* . . . was the largest Phase IIb ever done for macular degeneration, where *we demonstrated a statistically and clinically significant effect in a superiority trial over standard of care anti-VEGF – in this case, Lucentis therapy, showing a 62% comparative benefit over baseline standard of care Lucentis therapy*” Defendant Guyer further emphasized that the Phase 2b Trial “*hit both statistical and clinical significance with classic dose range finding* and a complete divergence at six month of the curves.”

74. The statements referenced above in ¶¶72-73 were materially false and misleading because Defendant Guyer knew, or recklessly disregarded, but failed to disclose that the results of the Phase 2b Trial were not indicative of Fovista’s efficacy, since those results were skewed by the fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group.

75. On June 10, 2015, during the Goldman Sachs Healthcare Conference, the following exchange occurred:

Terence Flynn – Goldman Sachs – Analyst:

. . . Just what was so compelling about the Phase 2 AMD data that you guys originally presented a couple of years ago? Just give us some of the context there for why that data was so interesting. And what drove to the decision to launch into this big Phase 3 program.

Defendant Patel:

. . . The benefit here not only showed the dose response curve with statistical significance benefits in the high dose compared to monotherapy anti-VEGF, high dose Fovista in combination with Lucentis versus Lucentis monotherapy for the dose response curve.

And over time, at every time point, there was splitting of the dose as well, and expanding benefit over time. *So obviously, given the statistical trends evidence, it was just a matter of repeating the same trial to maximize the success.* And go over to a longer time when that's required for registration.

76. Similarly, when Mr. Flynn asked for “an overview of the Phase 3 program to remind us of the design,” Defendant Guyer responded, in pertinent part, as follows:

Defendant Guyer:

. . . So our Phase 3 trials were designed to basically confirm our Phase 2b. The Phase 2b was the largest trial ever done in wet AMD, showed clinical and statistical significance. And our philosophy was to repeat them in the Phase 3 program, and to make all of the aspects of the trial as close to it as possible.

77. The statements referenced above in ¶¶75-76 highlighting the results of the Phase 2b Trial were materially false and misleading because Defendants knew, or recklessly disregarded, but failed to disclose that the results of the Phase 2b Trial were not indicative of Fovista's efficacy, since those results were skewed by the fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group. In addition, the statements referenced above in ¶¶75-76 that the Phase 3 Trials were “just a matter of repeating the same trial” as the Phase 2b Trial “to maximize the success,” that the “Phase 3 trials were designed to basically

confirm our Phase 2b,” and that Defendants’ “philosophy was to repeat [the Phase 2b Trial] in the Phase 3 program, and to make all of the aspects of the trial as close to it as possible” were materially false and misleading because Defendants knew, or recklessly disregarded, but failed to disclose that Defendants had made a significant change to the patient enrollment criteria for the Phase 3 Trials. Whereas the Phase 2b Trial had excluded patients with pure occult lesions, by requiring only the presence of SHRM for enrollment in the Phase 3 Trials, Ophthotech was permitting patients with pure occult lesions to be included in the Phase 3 Trials.

78. On August 5, 2015, Ophthotech issued a press release announcing that the Company expected to complete patient enrollment in its second Fovista Phase 3 Lucentis Trial during the fourth quarter of 2015, and expected “to report initial, topline data from both” Fovista Phase 3 Lucentis Trials “by the end of 2016.”

79. On October 26, 2015, Ophthotech issued a press release announcing that the Company had completed patient enrollment in the second Fovista Phase 3 Lucentis Trial.

80. On November 17, 2015, speaking at the Stifel Healthcare Conference, Defendant Guyer again highlighted the results of the Phase 2b trial, stating, in pertinent part, as follows:

. . . [O]ur Phase 2b program [was] the largest Phase 2 ever done in macular degeneration, a superiority trial where we showed statistical significant superiority in a 449-patient randomized controlled trial where Fovista plus Lucentis showed a 62% comparative benefit from baseline over Lucentis monotherapy alone . . .

* * *

If we turn again to our Phase 2b data, this, again, as I said, was the largest wet AMD Phase 2 ever done, as close to a Phase 3 as one can do. It showed a classic dose response curve, hit our statistical and clinical significant points, as well as, importantly, [showed] continued divergence throughout the trial. The maximum divergence is at six months, which is consistent with our mechanisms of action of anti-fibrosis. . . .

81. The statements referenced above in ¶80 highlighting the results of the Phase 2b Trial were materially false and misleading because Defendant Guyer knew, or recklessly disregarded, but

failed to disclose that the results of the Phase 2b Trial were not indicative of Fovista's efficacy, since those results were skewed by the fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group.

82. During the call, when an analyst asked about the protocol for administering separate injections of Lucentis and Fovista 30 minutes apart, Defendant Guyer responded by emphasizing how similar the Phase 2b and the Phase 3 Trials were in terms of design:

As far as the 30 minutes – and again, in our Phase 2 we had the injections given 30 minutes apart because we didn't know if there would be any issues with [intraocular pressure changes]. We saw none. Our main intraocular pressure was well below normal.

* * *

So we really don't think there's any problem. ***In the Phase 3***, we kept it 30 minutes because ***our mantra is don't change anything. You see too many companies make a lot of changes from Phase 2 to Phase 3, and you get surprises. So we were just being superstitious and changed nothing.***

83. The statements referenced above in ¶82 that Defendants' "mantra" for the Phase 3 Trials was "don't change anything," and that Defendants had "changed nothing" from the Phase 2b Trial were materially false and misleading because Defendant Guyer knew, or recklessly disregarded, but failed to disclose that Defendants had made a significant change to the patient enrollment criteria for the Phase 3 Trials. Whereas the Phase 2b Trial had excluded patients with pure occult lesions, by requiring only the presence of SHRM for enrollment in the Phase 3 Trials, Ophthotech was permitting patients with pure occult lesions to be included in the Phase 3 Trials.

84. On December 3, 2015, Ophthotech held a Research and Development Investor Day, during which Defendant Patel highlighted results of the Phase 2b Trial, stating, in pertinent part, as follows:

So you're obviously aware of our Phase 2B study which was a 449-patient study looking at the combination of Fovista and Lucentis versus monotherapy Lucentis.

* * *

And this was a very large trial, as you know, six months duration and ***the benefit of combination therapy over monotherapy was shown with statistical significant superiority of the 1.5 mg of Fovista.***

And the improvement was early and sustained and continued to expand over time and was not really related to any baseline features that typically drive visual acuity based on prognostic factors such as lesion size, baseline vision and baseline fluid. And all the parameters that Don talked about earlier of visual gain and visual loss that are clinically meaningful were consistently on the side of combination therapy.

85. The statements referenced above in ¶84 highlighting the results of the Phase 2b Trial were materially false and misleading because Defendant Patel knew, or recklessly disregarded, but failed to disclose that the results of the Phase 2b Trial were not indicative of Fovista's efficacy, since those results were skewed by the fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group. In addition, the statement referenced above in ¶84 that "the improvement" in visual acuity for patients in the Fovista combination group "was not really related to any baseline features that typically drive visual acuity . . . such as lesion size [or] baseline vision" was materially false and misleading because Defendant Patel knew, or recklessly disregarded, but failed to disclose that the apparent improvement was in fact driven by patients in the Fovista combination group having smaller lesions and better vision at baseline than patients in the Lucentis-only group.

86. On December 8, 2015, during the Oppenheimer Healthcare Conference, an analyst asked about potential differences between Ophthotech's Phase 2b Trial and Phase 3 Trials, and Defendant Guyer responded by emphasizing how similar the trials were:

Ling Wang – Oppenheimer & Co. – Analyst:

Great, so perhaps you can tell us your highlight of the Phase IIb data and the ongoing Phase III programs, perhaps in terms of the differences and similarities between these two trials.

Defendant Guyer:

Sure. So *the Phase III program is very similar to the Phase IIb. Our Phase IIb* was the largest Phase II trial ever done in wet AMD, almost as large as a Phase III. It *showed a classic dose response curve, as well as clinical and statistical significance over standard of care anti-VEGF monotherapy.*

We saw a maximum divergence of the curves at the last endpoint, six months, and the Phase III program really is to just confirm the Phase II, really similar in virtually every way short of the regulatory time point of 12 months, which is needed for regulatory [approval], versus six months.

* * *

But *basically, our goal was to confirm the Phase II, really not change anything at all.*

87. The statements referenced above in ¶86 highlighting the results of the Phase 2b trial were materially false and misleading because Defendant Guyer knew, or recklessly disregarded, but failed to disclose that the results of the Phase 2b Trial were not indicative of Fovista's efficacy, since those results were skewed by the fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group. In addition, the statements referenced above in ¶86 that "the Phase III program is very similar to the Phase IIb," that "the Phase III program really is . . . really similar in virtually every way short of the regulatory time point of 12 months," and that the goal of the Phase 3 Trials "was to confirm the Phase II, really not change anything at all" were materially false and misleading because Defendant Guyer knew, or recklessly disregarded, but failed to disclose that Defendants had made a significant change to the patient enrollment criteria for the Phase 3 Trials. Whereas the Phase 2b Trial had excluded patients with pure occult lesions, by requiring only the presence of SHRM for enrollment in the Phase 3 trials, Ophthotech was permitting patients with pure occult lesions to be included in the Phase 3 trials.

88. On January 11, 2016, speaking at the JP Morgan Healthcare Conference, Defendant Guyer reiterated the purportedly blockbuster results of the Phase 2b Trial, stating, in pertinent part, as follows:

. . . Our Phase 2b, the largest Phase 2b ever done in this disease showed a 62% additional benefit over standard of care monotherapy anti-VEGF therapy.

* * *

As most of you are aware, we conducted a **Phase 2b study**, the largest Phase 2b ever in wet AMD. There *was a superiority trial* and we have previously discussed the Phase 2b study, *which showed a 62% additional benefit over monotherapy anti-VEGF with statistical and clinical significance – a classic dose response curve with an early and sustained improvement. Early separation of the curve at three months increasing to maximum divergence at six months* and this is with no imbalances in the safety profile, but more important, *there was no baseline variable where the combination therapy was not superior to monotherapy nor was there a treatment endpoint where the combination was not superior to monotherapy. Therefore, the efficacy of combination therapy was beneficial to all subgroups.*

* * *

We are excited by our **strong results** in the Phase 2b study and look forward to the potential confirmatory data at year-end. *The strength of our Phase 2b data* and the recent new findings with Fovista combination therapy *are strongly suggestive of the disease modifying properties of Fovista.*

89. The statements referenced above in ¶88 highlighting the results of the Phase 2b trial were materially false and misleading because Defendant Guyer knew, or recklessly disregarded, but failed to disclose that the results of the Phase 2b Trial were not indicative of Fovista's efficacy, since those results were skewed by the fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group. Therefore, the results of the Phase 2b Trial were not "strongly suggestive of the disease modifying properties of Fovista," and Defendant Guyer had no reasonable basis to highlight "[t]he strength of [the] Phase 2b data."

90. On February 10, 2016, during the Leerink Partners Global Healthcare Conference, an analyst questioned Defendant Patel about potential differences between Ophthotech's Phase 2b and Phase 3 Trials, and Defendant Patel responded, in pertinent part, as follows:

Joe Schwartz – Leerink Partners – Analyst:

And a question we get a lot for any development program, but in particular yours since it was some time since your very large Phase II was done, is – *are there any differences between how the patients are being selected or any other differences in design for the Phase III for Fovista relative to the Phase II?*

Defendant Patel:

... You know *as far as differences between the Phase IIb study and the Phase III, there really aren't any differences that are material or significant in any way.*

And to be a little more specific about it, *I think one of the questions that often comes up is, is it a broader group of patients that are being studied?*

* * *

Now some questions have been raised about subtypes. And by that I really mean presence of neovascularization, whether it's above the retinal pigment epithelium, otherwise known as classic, if you were to look at it by fluorescein angiography, or if you look at it with the current imaging modality, which has high specificity, it's called sub-retinal hyper-reflective material [SHRM] as we are looking at it.

So, given its high specificity, *that's one change that we made, but it's actually no different in terms of [] the type of patients we are putting in.* And I think if somebody wants a proof of that, it's very simple. 93% of the patients in the Phase IIb study had the presence of sub-retinal hyper-reflective material. And the – given the variability between two physicians reading the fluorescein component of that is almost 30% or 40% in the variability.

So there are no changes that we can think of that are significant in any way.

Joe Schwartz – Leerink Partners – Analyst:

Okay. *So there's a lot of concurrence between the previous methodology based on old technology and the current methodology?*

Defendant Patel:

Yes, that's correct.

91. The statements referenced above in ¶90 characterizing SHRM as equivalent to classic lesions were materially false and misleading because SHRM may be present in patients whose lesions have either classic or occult components. Therefore, Defendant Patel knew, or recklessly disregarded, but failed to disclose that by requiring only the presence of SHRM for enrollment in the Phase 3 Trials, Defendants had made a significant change to the patient enrollment criteria that permitted patients with pure occult lesions to be included in the Phase 3 Trials. As a result, Defendant Patel had no reasonable basis to state that the Phase 3 Trials were “no different in terms of [] the type of patients we are putting in” and were not enrolling “a broader group of patients” than the Phase 2b Trial, or that “there really aren’t any differences that are material or significant in any way” between the Phase 2b and Phase 3 Trials. In addition, Defendant Patel misleadingly failed to correct the analyst’s mistaken belief that they had merely changed the “methodology” used to determine patient eligibility in the Phase 3 Trials, when, in fact, they had materially changed the enrollment criteria.

92. On February 24, 2016, Defendants held an earnings conference call with analysts and investors. During the call, Defendant Patel responded to an analyst’s question about whether Ophthotech planned to finally publish the results of the Phase 2b Trial – which had been completed nearly four years earlier – in pertinent part, as follows:

Yigal Nochomovitz – Citigroup – Analyst:

... And obviously you published the Phase 1 data last year. *We’ve just been getting questions from clients regarding potential to see the Phase 2 study in print. Any plans for that this year?*

Defendant Patel:

We plan to submit the Phase 2 paper, *I think it’s just an issue more than anything else of priority and getting the key aspects related to the Phase 3 trial going and subsequently finishing enrollment. That is really responsible for what some may perceive as delay in getting the Phase 2 paper out.* But I can assure you that we’ve

put a lot of effort into it lately and as we added more individuals to our team and we expect to have that submitted very shortly.

93. The statements referenced above in ¶92 were materially false and misleading because in truth, Defendants were delaying the publication of the Phase 2b Trial so that they could continue to sell their stock at artificially inflated prices before investors discovered that the results of the Phase 2b Trial were skewed by the fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group.

94. During the call, an analyst asked about potential differences in patient characteristics between the Phase 2b and Phase 3 Trials, and Defendants responded, in pertinent part, as follows:

Joseph Schwartz – Leerink Partners – Analyst:

... I was wondering if you could speak to whether, on a blinded basis, whether the baseline characteristics for the two Phase 3 trials are more or less consistent with Phase 2 and your expectations for who would be enrolled in Phase 3. And whether there are any differences between the two Phase 3 studies, again on a blinded basis? Baseline characteristics only.

Defendant Patel:

... We wouldn't know the baseline characteristics. Of course the [Phase 3] studies, the database hasn't been closed and one of the Phase 3 trial is ongoing. I think as far as from a general standpoint, the inclusion criteria are quite similar between the Phase 2b and 3 and I think we've addressed that.

There's no reason for us to believe that there would be, especially the key characteristics related to baseline vision, lesion compositions and sizes of lesions, et cetera should be quite similar. And don't forget that the inclusion in this trial just as it was in the Phase 2b, it's done by an independent reading center. It's the same reading center and that process is probably the single most variable in making sure that the patient characteristics of relevance are similar.

Defendant Guyer:

I would also just add that the Fovista effect has been very, very broad as we've shown many times. Any way you cut the data as far as baseline characteristics, as far as (inaudible) endpoints, the Fovista combination group always does better than the anti-VEGF monotherapy control group. As Samir said, while we believe because the criteria are so similar that most likely the patient population should be

similar, because of this very broad effect even in anti-VEGF treatment failures we see an effect in the Fovista expansion trial.

It really should not matter, we're talking about a drug that we believe will show a broad effect among all comers. And so far that is what the data shows. We, again, have not seen the baseline demographics; we won't until we get the data and while ***we expect them to be close to Phase 2***, what's been very exciting is just how broad the effect of Fovista has looked in both naive and limited data with treatment failures across the board any way you cut the data.

95. The statement referenced above in ¶94 that “the inclusion criteria are quite similar between the Phase 2b and 3” was materially false and misleading because Defendant Patel knew, or recklessly disregarded, but failed to disclose that Defendants had made a significant change to the patient enrollment criteria for the Phase 3 Trials. Whereas the Phase 2b Trial had excluded patients with pure occult lesions, by requiring only the presence of SHRM for enrollment in the Phase 3 Trials, Ophthotech was permitting patients with pure occult lesions to be included in the Phase 3 Trials. Because the changed enrollment criteria meant that the estimated 40% of wet AMD patients with pure occult lesions were eligible to participate in the Phase 3 Trials, Defendants did, in fact, have “reason . . . to believe” that “lesion compositions” would be different in the Phase 3 Trials, and had no reasonable basis to “expect” that patient baseline demographics in the Phase 3 Trials would be “close to Phase 2,” or to “believe . . . that most likely the patient population should be similar.” In addition, use of “the same reading center” was not “the single most variable in making sure that the patient characteristics of relevance [were] similar.” Rather, the enrollment criteria was the most important factor – and the changed enrollment criteria meant that patient characteristics were unlikely to be similar despite use of the same reading center. Furthermore, “the data” from the Fovista clinical trials “so far” did not “show[]” that Fovista had “a broad effect among all” wet AMD patients, because when images of patients’ lesions were examined at the end of Ophthotech’s phase 1 clinical trial, the occult components of the lesions appeared to be unaffected by treatment with Fovista.

96. Also on February 24, 2016, Defendant Guyer spoke at the RBC Capital Markets Healthcare Conference, and again highlighted the results of the Phase 2b trial, stating, in pertinent part, as follows:

. . . [W]e have previously discussed *our Phase 2 trial* which *showed a 62% additional benefit over monotherapy anti-VEGF with statistical and clinical significance that showed a classic dose response curve with an early and sustained improvement, and early separation of these curves at three months that increased to maximum divergence at our last patient follow-up point of six months*. There were no imbalances in the safety profile in this study, but more importantly, *there was no baseline variable where the combination therapy was not superior to monotherapy, nor was there a treatment endpoint, where the combination with Fovista was not superior to monotherapy and anti-VEGF. Therefore, the efficacy of combination treatment* was focused or *was beneficial to all subgroups*.

* * *

The strength of our Phase 2b data and the recent new findings with Fovista combination therapy *are strongly suggestive of the disease-modifying properties of Fovista*.

97. The statements referenced above in ¶96 highlighting the results of the Phase 2b trial were materially false and misleading because Defendant Guyer knew, or recklessly disregarded, but failed to disclose that the results of the Phase 2b Trial were not indicative of Fovista's efficacy, since those results were skewed by the fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group. Therefore, the results of the Phase 2b Trial were not "strongly suggestive of the disease-modifying properties of Fovista, and Defendants had no reasonable basis to highlight "[t]he strength of our Phase 2b data."

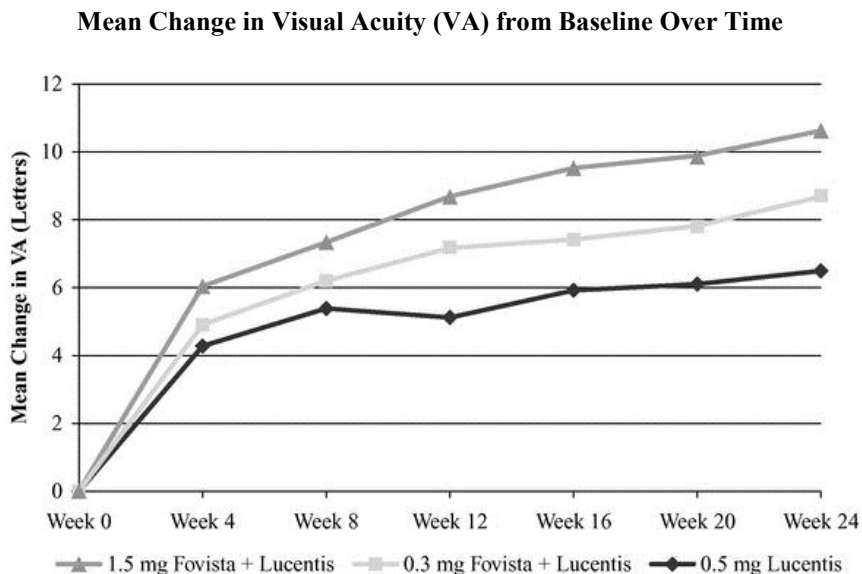
98. On February 26, 2016, Ophthotech filed its annual report for the year ended December 31, 2015 with the SEC on Form 10-K, which was signed by Defendants Guyer and Patel. Just as the 2014 Form 10-K had, the 2015 Form 10-K highlighted the results of the Phase 2b Trial and its similarity to the ongoing Phase 3 Trials, stating, in pertinent part, as follows:

In our completed Phase 2b clinical trial, the combination of 1.5 mg of Fovista and Lucentis demonstrated statistically significant superiority compared to Lucentis

monotherapy based on the primary endpoint of mean change in visual acuity from baseline at 24 weeks, providing a 62% comparative benefit from baseline. Our Phase 3 clinical program builds on and incorporates significant aspects from the design of our Phase 2b clinical trial.

* * *

[T]he following graph sets forth the mean change in visual acuity from baseline for each treatment group in our Phase 2b clinical trial over the course of the trial:



We observed a visual benefit in patients treated with the combination of 1.5 mg of Fovista and Lucentis early in and sustained over the course of treatment. The relative magnitude of visual benefit increased over the study period. We believe that these results suggest that Fovista may provide benefit to patients when used over time in combination with Lucentis.

99. The statements referenced above in ¶98 were materially false and misleading because Defendants knew, or recklessly disregarded, but failed to disclose that the results of the Phase 2b Trial were not indicative of Fovista’s efficacy, since those results were skewed by the fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group. In addition, the statement referenced above in ¶98 that “[o]ur Phase 3 clinical program builds on and incorporates significant aspects from the design of our Phase 2b clinical trial” falsely and misleadingly communicated that the Phase 3 Trials were similar in design

to the Phase 2b Trial, when in truth, Defendants had made a significant change to the patient enrollment criteria for the Phase 3 Trials. Whereas the Phase 2b Trial had excluded patients with pure occult lesions, by requiring only the presence of SHRM for enrollment in the Phase 3 Trials, Ophthotech was permitting patients with pure occult lesions to be included in the Phase 3 Trials.

100. The 2015 Form 10-K also reiterated the purported similarity between the Phase 2b and Phase 3 Trials' design and patient eligibility criteria, stating, in pertinent part, as follows:

While we have modified the methodology used to determine a patient's eligibility under certain of the inclusion and exclusion criteria for our Phase 3 clinical trials as compared to our Phase 2b clinical trial, we have made no meaningful changes to the inclusion and exclusion criteria in these Phase 3 clinical trials from those we used in our Phase 2b clinical trial. We expect that this will result in the enrollment of a patient population similar to the patient population enrolled in our Phase 2b clinical trial.

* * *

We have made no meaningful changes to the inclusion and exclusion criteria in these Phase 3 clinical trials from those we used in our Phase 2b clinical trial. However, we have modified the methodology used to determine a patient's eligibility under certain of the inclusion and exclusion criteria for our Phase 3 clinical trials as compared to our Phase 2b clinical trial. For our Phase 2b trial, we assessed patient eligibility based on the fluorescein angiographic pattern of the choroidal neovascular membrane. Since the most commonly employed modality for imaging, diagnosing and managing neovascular AMD is currently SD-OCT, we have modified the methodology to determine the patient's eligibility to include SD-OCT criteria. To ensure that uniform criteria are applied in characterizing patients' neovascular lesions, we have engaged a centralized reading center to review the SD-OCT, fluorescein angiograms and fundus images of each patient's affected eye.

* * *

For our Phase 3 clinical trials, the reading center uses all three of these imaging modalities, fluorescein angiography, SD-OCT and fundus images, to assess the eligibility of patients based on the presence of abnormal new blood vessels relative to the RPE at the time of enrollment.

101. The statements referenced above in ¶100 were materially false and misleading because Defendants knew, or recklessly disregarded, but failed to disclose that Defendants had not merely "modified the ***methodology*** used to determine a patient's eligibility" in the Phase 3 Trials –

they had modified the enrollment criteria. In truth, Defendants *had* “made [a] meaningful change[] to the inclusion and exclusion criteria in the[] Phase 3 clinical trials from those [] used in [the] Phase 2b clinical trial.” Whereas the Phase 2b Trial had excluded patients with pure occult lesions, by requiring only the presence of SHRM for enrollment in the Phase 3 Trials, Ophthotech was permitting patients with pure occult lesions to be included in the Phase 3 Trials. Because the changed enrollment criteria meant that the estimated 40% of wet AMD patients with pure occult lesions were eligible to participate in the Phase 3 Trials, Defendants had no reasonable basis to “expect that” the Phase 3 Trials would “enroll[] . . . a patient population similar to the patient population enrolled in [the] Phase 2b clinical trial.”

102. In addition, the 2015 Form 10-K contained an identical description of the imaging technologies used to detect lesion characteristics to that contained in the 2014 Form 10-K:

. . . The process for determining whether or not a wet AMD patient has pure occult choroidal neovascularization has evolved considerably in the United States and European Union over the last five years, with SD-OCT replacing fluorescein angiography as the diagnostic standard. There is significant variability and inconsistency among physicians and reading centers with respect to the determination of the presence and amount of the occult component of lesions using fluorescein angiography. Different reading centers may categorize a patient differently on the basis of the same image if fluorescein angiography is used to assess the occult component of choroidal neovascularization. We believe the use of SD-OCT to assess choroidal neovascularization at the time of enrollment in our Phase 3 clinical trials will alleviate some of the variability and inconsistency inherent in using fluorescein angiography. SD-OCT will be used to assess the characteristics of abnormal new vessels, which historically, using fluorescein angiography, have been associated with the subtype occult neovascularization. SD-OCT is the current standard of imaging of wet AMD patients and we believe that the use of SD-OCT will provide a more precise analysis of the anatomical differences between the various angiographic subtypes of CNV lesions in neovascular AMD.

* * *

We believe that use of . . . the latest imaging technologies enables us to confirm patient eligibility and properly classify neovascular characteristics and the associated leakage in an accurate and standardized manner prior to enrolling patients in the trial.

103. The statements referenced above in ¶102 were materially false and misleading because they characterized SD-OCT imaging as a considerable advancement in “[t]he process for determining whether or not a wet AMD patient has pure occult” lesions, which would lead to more accurate categorization of patients by lesion subtype, but failed to disclose that Defendants had made a significant change to the patient enrollment criteria for the Phase 3 Trials with respect to lesion subtypes. Whereas the Phase 2b Trial had excluded patients with pure occult lesions, by requiring only the presence of SHRM for enrollment in the Phase 3 Trials, Ophthotech was permitting patients with pure occult lesions to be included in the Phase 3 Trials.

104. On May 4, 2016, Defendants held an earnings conference call with analysts and investors, during which an analyst specifically asked about the inclusion of patients with occult lesions in the Phase 3 Trials, and Defendant Patel explicitly denied that patients with occult lesions were eligible for inclusion in the Phase 3 Trials:

Gbola Amusa – Chardan Capital Markets – Analyst:

... Sorry to rehash an old topic, but our conversations with investors seems to touch on investor questions about *the composition of your trials, but with regards to occult versus classic patients. As you’re getting close to completing enrollment, could you tell us what percentage of your patients have occult wet AMD and if you wouldn’t mind just frame the issue just so we can understand . . . where you are in Phase III versus Phase II.*

Defendant Patel:

... It’s been addressed multiple times and nothing has changed. *It’s a very simple answer. There is no occult in our pivotal [Phase 3] study like [the] Phase II-B study as well.* So I think it’s sufficed to state *the definition of occult requires [fluorescein] angiogram*, and by definition that would make sure that somebody saying occult included is when you don’t use fluorescein how can that statement be made. So it doesn’t – we don’t understand it. It doesn’t make any sense.

Secondly, *the [SHRM] material*, which we’ve covered, which is the entry point is – requires patients that have neo-vascular complex according to its definition above the RPE. *That would itself, by analogy, preclude occult.* So I can’t really give any further guidance where the perception that there is occult comes from. . . .

105. The statements referenced above in ¶104 that “[t]here is no occult in our pivotal [Phase 3] study like [the] Phase [2b] study” because “the definition of occult requires [fluorescein] angiogram,” and that the definition of SHRM “preclude[s] occult” were materially false and misleading because SHRM may be present in patients whose lesions have either classic or occult components. Therefore, Defendant Patel knew, or recklessly disregarded, but failed to disclose that patients whose lesions had occult characteristics were in fact eligible for inclusion in the Phase 3 Trials.

106. On June 7, 2016, speaking at the Goldman Sachs Global Healthcare Conference, Defendant Patel again highlighted the Phase 2b Trial’s results, stating, in pertinent part, as follows:

Defendant Patel:

. . . So, for us to have had a statistically significant benefit with respect to superiority of a[n] approximately four-letter benefit, which translate into 62% additional efficacy from baseline, it’s very exciting.

And all the clinically meaningful endpoints that are typically looked at – three, four, five lines of vision gain; 20/40 or better; 20/25 or better – all were on the side of benefit of Fovista. It gives you a great deal of confidence about the clinical meaningfulness, clinical significance and robustness of the data.

107. The statements referenced above in ¶106 highlighting the results of the Phase 2b trial and the “robustness of the data” were materially false and misleading because Defendant Patel knew, or recklessly disregarded, but failed to disclose that the results of the Phase 2b Trial were not indicative of Fovista’s efficacy, since those results were skewed by the fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group.

108. During the conference, when Defendant Patel was again asked about potential differences in patient inclusion criteria between the Phase 2b and Phase 3 Trials, he emphasized that

there were “no material changes,” and again explicitly denied that patients with occult lesions were eligible for inclusion in the Phase 3 Trials:

Terence Flynn – Goldman Sachs – Analyst:

... Maybe as you compare the Phase 2 to the Phase 3, remind us what some of the changes were. I think one was duration. Obviously you touched on this. But any other key changes that were made? I know your goal is to reproduce as much as possible, but as we think about similarities, differences, between the Phase 2 and the Phase 3 program, maybe just remind us what some of the differences are.

Defendant Patel:

... [S]o, we've worked pretty hard in trying to keep virtually all the parameters the same. I think that, if you look at the entry criteria for vision; if you look at – of course, we had to increase the number of sites, because it's a higher sample size study. I think that's a bit different. But virtually anything that's material is – has been kept the same.

... [A] lot of people have pointed out that perhaps occults are being enrolled in the trial, and it's simply not the case, because what – the definition of occult is driven by fluorescein angiogram, and when we started the study, the Phase 2b study, OCT was not used ubiquitously [as] standard of care for imaging.

It is now, and it would be very unusual – in fact, physicians have come out and told us that to use fluorescein to enter patients commercially – not be the right thing to do. And in fact, given the specificity, it measures the lesions – for the type of lesions that we were looking at in the Phase 2, it's identical. So, it's not really an issue.

So, we've gone through great care of making sure virtually all material aspects of the trials – inclusion, exclusion, and it's the same reading center. So, we feel very good about it.

And if you look at this point last (inaudible) – if you look, for example, in anti-VEGF monotherapy trials, you'll see a great deal of variability on how the lesions are read in terms of its size based on fluorescein. And it's a very noisy test. So, I'm just touching upon that, because some people have brought up the issue that maybe – that there are some changes; but really [there] are no material changes.

Terence Flynn – Goldman Sachs – Analyst:

So, you think by using OCT you have a more homogeneous population? Is that the right way to think about it . . . ?

Defendant Patel:

... [F]irst of all, I think it's very important to understand that in none of the trials at all has there been any changes, one can say that subtypes really matter. They don't when you adjust them for size.

109. The statements referenced above in ¶108 that “virtually all the parameters” and “anything that’s material . . . ha[d] been kept the same” between the Phase 2b and Phase 3 Trials, that Defendants had taken “great care” to make sure “virtually all material aspects of the trials” such as “inclusion [and] exclusion” criteria were the same, that “some people have brought up the issue that maybe . . . there are some changes; but really [there] are no material changes,” and that “it’s very important to understand that in none of the trials at all has there been any changes” were materially false and misleading because Defendant Patel knew, or recklessly disregarded, but failed to disclose that Defendants had made a significant change to the patient enrollment criteria for the Phase 3 Trials. Whereas the Phase 2b Trial had excluded patients with pure occult lesions, by requiring only the presence of SHRM for enrollment in the Phase 3 Trials, Ophthotech was permitting patients with pure occult lesions to be included in the Phase 3 Trials. In addition, the statements referenced above in ¶108 that it was “simply not the case” that “occults are being enrolled in the [Phase 3] trial[s],” and that the use of SD-OCT imaging to screen patients for enrollment in the Phase 3 Trials assured the inclusion of patients with “identical” “types of lesions” to those Ophthotech was “looking at in the Phase 2,” such that differences in lesion types between trials was “not really an issue” were materially false and misleading because Defendant Patel knew, or recklessly disregarded, but failed to disclose that patients whose lesions had occult characteristics were in fact eligible for inclusion in the Phase 3 Trials.

110. On June 20, 2016, Ophthotech issued a press release announcing that the Company had completed patient enrollment in the Fovista Phase 3 Eylea/Avastin Trial.

111. On August 3, 2016, Defendants held an earnings conference call with analysts and investors, during which an analyst asked about the possibility that the Lucentis monotherapy group had underperformed in the Phase 2b Trial, and Defendant Patel responded, in pertinent part, as follows:

Brett Larson – Leerink Partners – Analyst:

. . . First on Fovista, ***when considering the Phase 2b results, to assess what results do we expect from these upcoming Phase 3 studies, we’ve heard consistently from investors and clinicians that*** they recognize there are two key characteristics that – one providing tailwind, one the other headwinds to achieving comparable efficacy, one being that ***patients showed lower visual acuity gains in the Lucentis arm of the Phase 2 study than one might have expected compared to other studies that have been conducted.*** But on the other hand, now you have a trial endpoint that is one year versus six months previously. ***So I’d love to hear your thoughts on how significant of a driver one of these factors is versus another, and if there are any other key characteristics that have changed leading to these Phase 3 results that you’d like to highlight, that increase or temper your confidence.***

Defendant Patel:

* * *

So the underperformance, which is what you are referring to, we think that’s quite irrational. First, cross-trial comparisons are not scientifically valid so that in it itself is, you know, we think not really valid. ***Secondly, I think to say that one arm underperformed, but somehow magically the combination arm wouldn’t in a very large trial where this randomization and baseline variables are similar, that would be quite irrational.***

112. The statements referenced above in ¶111 were materially false and misleading because Defendant Patel knew, or recklessly disregarded, but failed to disclose that the “baseline variables” were not “similar” between the control and therapy groups in the Phase 2b Trial, since patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group. Consequently, Defendant Patel had no reasonable basis to dismiss investors’ concerns that the results of the Phase 2b Trial might not be indicative of Fovista’s efficacy as “quite irrational.”

113. On September 13, 2016, during the Morgan Stanley Global Healthcare Conference, Defendant Patel again dismissed concerns that the results of the Phase 2b Trial might not be indicative of Fovista's efficacy:

Matthew Harrison – Morgan Stanley – Analyst:

... So then a couple key questions that we get around differences between Phase 2 and Phase 3, maybe if we could just talk about them. One that's, I think, probably highlighted ... more by competitors in the marketplace, but I think it has become an investor question because of that. Is that you saw 4-letter difference in Phase 2. Some people point to the fact that that's within the range of variability of differences that you see between different studies. So I guess the question is, how confident do you feel in that result that you saw in Phase 2, and that it's not just, as some people might suggest, due to variability in the reading.

Defendant Patel:

... [A] difference of 4 letters, I think, it's been stated recently quite well that that's a remarkable difference, especially when you have 62% additional efficacy from baseline. So each trial has to look at the relative benefit compared to its own. And when we talk about variability, the variability is already taken into account when you have variance in the measurement that's measuring, and standard deviations, et cetera. So statistical significance already takes that into account.

So when we say a 4-letter difference, we're saying it's 4 letters and real for that particular trial, if it's conducted with adequate power and adequate conduct. And that analysis – and if you take the Phase 2 study, for example, that 4 letters led to remarkable differences in three, four and five lines of vision gained, 20/40 or better, 20/25 or better, 20/125 or worse. So these are really clinically meaningful end points and there was a significant difference between the groups. So that's what the 4 letters translate into.

So in summary, yes, it is true that two different trials can give you different numbers. But that's sort of like saying, if you had blood pressure measurement to do in oncology, two different oncology trials, your baseline and final blood pressures may be very different.

114. The statements referenced above in ¶113 were materially false and misleading because Defendant Patel knew, or recklessly disregarded, but failed to disclose that the results of the Phase 2b Trial were not indicative of Fovista's efficacy, since those results were skewed by the fact

that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group.

115. During the conference, Defendant Patel was directly asked whether “additional criteria, such as SHRM” in the Phase 3 Trials “could lead to “potential difference[s]” [in] “baseline characteristics between Phase 2 and Phase 3” Trials. In response, Patel emphasized the “almost identical” design of the trials, and insisted that it was “simply not true” that patients with occult lesions were eligible for inclusion in the Phase 3 Trials:

Matthew Harrison – Morgan Stanley – Analyst:

... Can we talk a little bit about baseline characteristics? I think it's another area that people try and understand. And so I think you've added some additional criteria, such as SHRM and some other things to Phase 3. Can you just talk about why you did that and then what the difference is, or the potential difference between baseline characteristics between Phase 2 and Phase 3, and what the reasoning for that was?

Defendant Patel:

... So just as a general matter, I mean I think, at least from other trials that I'm used to, at least to the best of my knowledge, it's quite rare to have a Phase 3 be as analogous and almost identical to a Phase 2 as ours is.

* * *

So it's quite remarkable. To the best of my knowledge, at least in ophthalmology, this is about as close as you can get, where the Phase 3 is like the Phase 2. And I could argue that's probably the case in all therapeutic areas, when you compare the Phase 2 and Phase 3. So it's remarkable. It's almost identical.

* * *

As far as the patients are concerned, absolutely we think that – first of all, *it's a misconception to think that all comers operate in the Phase 3. It's simply not true.* What the – as *the OCT and the definitions that is used for the subretinal hyper-reflective material [SHRM] is the same as the presence of what the classic conveys by fluoranthene angiogram.* That is the presence of neovascularization above the RPE and below the photoreceptor. We just call classic by fluoranthene.

And our definition by the same reading center, *using these SD-OCT are the same group of patients. And that's been looked at by the reading center.*

* * *

What is relevant for the investors here is to understand that this particular reading center is using the same definition of the presence of neovascularization over the RPE. And there's no reason for us to believe that that constitutes a different group of patients.

116. The statements referenced above in ¶115 that “it’s quite rare to have a Phase 3 be as analogous and almost identical to a Phase 2 as ours is,” that “this is about as close as you can get, where the Phase 3 is like the Phase 2,” that the similarities between the two phases were “quite remarkable” and the trials were “almost identical,” and that it was a “misconception” and “simply not true” that patients with all lesion types were eligible for inclusion in the Phase 3 Trials were materially false and misleading because Defendant Patel knew, or recklessly disregarded, but failed to disclose that by requiring only the presence of SHRM, Defendants had made a significant change to the patient enrollment criteria for the Phase 3 Trials, and the changed criteria meant that patients with pure occult lesions were eligible for inclusion in the Phase 3 Trials. In addition, the statements referenced above in ¶115 that SHRM was “the same as . . . classic” lesions, that “the same definition” of patients’ lesion characteristics was being used in the Phase 3 Trials, and that the enrollment criteria for the Phase 3 Trials captured “the same group of patients” as the Phase 2b Trial were materially false and misleading because Defendant Patel knew, or recklessly disregarded, but failed to disclose that SHRM may be present in patients whose lesions have either classic or occult components – including patients with pure occult lesions. Because the changed enrollment criteria meant that the estimated 40% of wet AMD patients with pure occult lesions were eligible to participate in the Phase 3 Trials, Defendant Patel did in fact have “reason . . . to believe that . . . a different group of patients” would be enrolled in the Phase 3 Trials. Finally, Defendant Patel’s response was misleading because he failed to correct the analyst’s mistaken belief that SHRM was

merely an “additional criteria” in the Phase 3 Trials. In fact, patient eligibility for the Phase 3 Trials required *only* the presence of SHRM.

117. On October 31, 2016, Ophthotech issued a press release announcing that the Phase 2b Trial had finally been published in Ophthalmology®, the Journal of the American Academy of Ophthalmology. The press release reiterated that “*Patients receiving the combination of Fovista® (1.5 mg) and Lucentis® (0.5 mg) gained a mean of 10.6 letters of vision on the ETDRS standardized chart at 24 weeks, compared to 6.5 letters for patients receiving Lucentis® monotherapy (p=0.019). This represents a 62% additional benefit from baseline.*” In the press release, Defendants Patel and Guyer commented, in pertinent part, as follows:

Defendant Patel:

. . . *The strength of results* of this large trial represent the basis for our Fovista® in combination with anti-VEGF therapy Phase 3 registration program for the treatment of wet AMD.

Defendant Guyer:

We would like to thank all the participating physicians, patients and their staff for their splendid effort in this *well conducted trial*. . . .

118. The statements referenced above in ¶117 highlighting the results of the Phase 2b trial were materially false and misleading because Defendants knew, or recklessly disregarded, but failed to disclose that the results of the Phase 2b Trial were not indicative of Fovista’s efficacy, since those results were skewed by the fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group. As a result, Defendants had no reasonable basis to highlight the “strength of results” of the Phase 2b Trial, or to characterize the trial as “well conducted.”

119. In the publication itself, Ophthotech disclosed the 17% baseline imbalance in lesion size between patients in the Lucentis-only group and patients in the Fovista combination group. One

week later, on November 8, 2016, Defendants held their first conference call with analysts and investors since the publication of the Phase 2b Trial. During the call, when an analyst from Morgan Stanley asked whether the baseline imbalance in lesion size between the Lucentis-only group and the Fovista combination group may have impacted the results of the Phase 2b Trial, Defendant Patel dismissed such concerns as having “no validity”:

Unidentified Participant – Analyst:

... A lot of investors have been focused on baseline imbalance and lesion size as [] impacting the strength of the Phase 2 data. Could you give your views on how important lesion size is as a prognostic factor in these trials, and if you think that impacted the Phase 2 data?

Defendant Patel:

First, I think the publication speaks for itself. There’s no discussion of that. It’s a very – it’s a top journal. You would expect that something – I think that tells you there is no validity to the statement of impact of the data because of lesion size measurement in itself. Just to give you some background.

I don’t know why someone would think that would affect at that level in terms of a one-to-one correlation with lesion size, nor are we aware of any uniform or constant or consistent trends.

120. The statements referenced above in ¶119 were materially false and misleading because Defendant Patel had no reasonable basis to dismiss investors’ concerns that the results of the Phase 2b Trial were impacted by the baseline imbalance in lesion size as having “no validity.” In fact, since larger lesions tend to be more chronic, severe, and difficult to treat, patients receiving Fovista in the Phase 2b Trial were more likely to experience an improvement in visual acuity because they had smaller lesions to begin with, and that improvement was not necessarily due to Fovista.

The Truth Is Revealed

121. On December 12, 2016, before the markets opened, Ophthotech stunned investors when the Company issued a press release announcing the results of the Fovista Phase 3 Lucentis

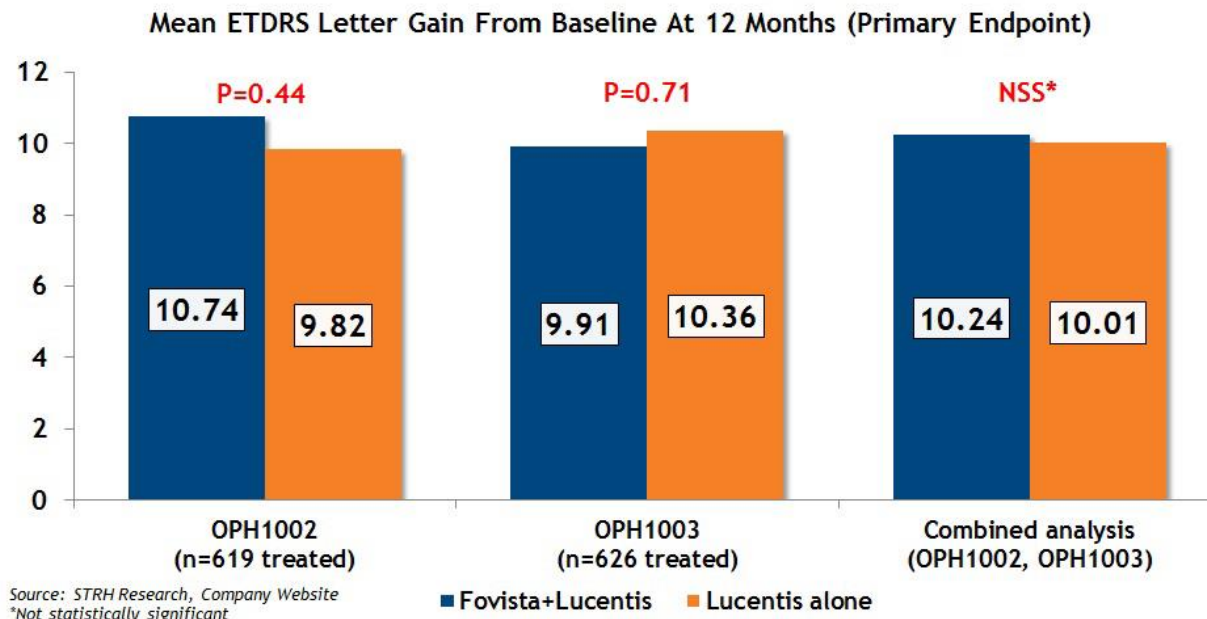
Trials and disclosing that “[n]o benefit [was] observed upon [the] addition of Fovista® to monthly Lucentis® regimen for the treatment of wet [AMD.]” Specifically, the combined analysis of both Phase 3 Trials showed that patients who received Fovista in combination with Lucentis demonstrated a mean gain in visual acuity of 10.24 letters on the ETDRS standardized eye chart at 12 months, a non-statistically significant improvement over the mean gain in visual acuity of 10.01 letters observed in the control patient group that received Lucentis monotherapy. The press release stated, in pertinent part, as follows:

Ophthotech . . . today announced that *the pre-specified primary endpoint of mean change in visual acuity at 12 months was not achieved in its two pivotal Phase 3 clinical trials* investigating the superiority of Fovista® (pegpleranib) anti-PDGF therapy in combination with Lucentis® (ranibizumab) anti-VEGF therapy compared to Lucentis® monotherapy for the treatment of wet age-related macular degeneration (AMD). *The addition of Fovista® to a monthly Lucentis® regimen did not result in benefit as measured by the mean change in visual acuity at the 12 month time point.*

* * *

The combined analysis from the two trials (OPH1002 and OPH1003) showed that patients receiving Fovista® combination therapy gained a mean of 10.24 letters of vision on the Early Treatment of Diabetic Retinopathy Study (ETDRS) standardized chart at 12 months, compared to a mean gain of 10.01 ETDRS letters for patients receiving Lucentis® monotherapy, a difference of 0.23 ETDRS letters. In OPH1002, consisting of 619 treated patients, subjects receiving Fovista® combination therapy gained a mean of 10.74 letters of vision on the ETDRS standardized chart at 12 months, compared to a mean gain of 9.82 ETDRS letters in patients receiving Lucentis® monotherapy, a resulting difference of 0.92 ETDRS letters (p=0.44). In OPH1003, consisting of 626 treated patients, subjects receiving Fovista® combination therapy gained a mean of 9.91 letters of vision on the ETDRS standardized chart at 12 months, compared to a mean gain of 10.36 ETDRS letters in patients receiving Lucentis® monotherapy, a resulting difference of -0.44 ETDRS letters (p=0.71). *None of these results of the pre-specified primary efficacy analysis were statistically significant.*

122. The primary endpoint results of the Fovista Phase 3 Lucentis Trials are illustrated in the following chart:



123. In response to this news, the price of Ophthotech common stock plummeted approximately **86%** on more than 30 times the previous day's trading volume, from a closing price of \$38.77 per share on Friday, December 9, 2016, to close at \$5.29 per share on Monday, December 12, 2016. The price of Ophthotech common stock continued to decline over the next three trading days, closing at \$4.86 per share on December 15, 2016.

124. Following the news that the Phase 3 Trials were a complete failure, analysts issued reports expressing surprise and confusion. For example, a December 13, 2016 Gabelli & Company analyst report stated: “[W]e *considered the potential causes for concern*,” including Ophthotech “*management significantly reducing their ownership stake ahead of results[], but ultimately we chose to believe that these elements could be explained away in the face of what looked like impressive Phase II results. Rather than being red herrings, these were red flags Fovista simply doesn’t work.*” The report concluded that “at this point it appears that the Fovista program . . . is dead,” and “we see little reason to own shares”

125. Similarly, a December 12, 2016 BTIG analyst report stated that “[w]e are obviously surprised and disappointed in the results, given the robust Phase IIb data,” and a Leerink analyst report issued the same day noted that “[t]hese are unexpected results that were not in line with our expectations.” A December 12, 2016 Chardan Capital Markets analyst report stated that: “We found no material evidence of Fovista efficacy communicated in the press release and therefore model zero probability of success for Fovista going forward. . . .”

Post-Class Period Events

126. The fallout from Fovista’s failure continued to reverberate after the end of the Class Period. On December 16, 2016, Ophthotech announced that it would stop treating patients currently in the second 12 months of the Fovista Phase 3 Lucentis Trials. The Company also announced that it would reduce its workforce by approximately 80%, to just 20 to 30 employees.

127. On January 12, 2017, Defendant Patel resigned from his positions at the Company, effective the following day.

128. On February 1, 2017, Ophthotech acknowledged that it would be forced to change its business strategy in light of Fovista’s failure. The Company announced that it had retained Leerink Partners LLC as its financial advisor in connection with its “plan to review its strategic alternatives[.]” “Without limiting any option,” Ophthotech planned to “explore obtaining rights to additional products, product candidates and technologies to treat ophthalmic diseases.”

129. Then, on April 24, 2017, Ophthotech announced that Defendant Guyer was stepping down from his positions as CEO and Chairman of the Board of Directors, and would “transition” to the newly-created advisory position of Executive Chairman, effective July 1, 2017.

130. On August 14, 2017, any lingering hopes for Fovista were dashed when Ophthotech announced that the Fovista Phase 3 Eylea/Avastin Trial had likewise failed to show a statistically significant improvement in visual acuity upon the addition of Fovista, as compared to anti-VEGF

monotherapy. As a result, the Company would stop treating patients currently in the second 12 months of the trial, thereby ending its Fovista clinical program. In Ophthotech's Form 10-Q filed with the SEC on November 8, 2017, the Company confirmed that it had "no future plans to develop Fovista in wet AMD."

131. In light of the failure of the Fovista phase 3 program, Novartis notified the Company on October 23, 2017 that it had elected to terminate its agreement with Ophthotech, effective immediately.

132. At the time of the filing of this Complaint, Ophthotech's common stock was trading well below \$3.00 per share.

Additional Scienter Allegations

133. As alleged herein, Defendants acted with scienter in that Defendants knew, or recklessly disregarded, that the public documents and statements they issued or disseminated in the name of the Company or in their own name during the Class Period were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. Defendants, by virtue of their receipt of information reflecting the true facts regarding Ophthotech, their control over, and/or receipt and/or modification of Ophthotech's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Ophthotech, were active and culpable participants in the fraudulent scheme alleged herein.

134. Defendants knew and/or recklessly disregarded the falsity and misleading nature of the information which they caused to be disseminated to the investing public. The fraudulent scheme described herein could not have been perpetrated during the Class Period without the

knowledge and complicity or, at least, the reckless disregard of the personnel at the highest levels of the Company, including the Individual Defendants.

135. The Individual Defendants, because of their positions with Ophthotech, controlled the contents of the Company's public statements during the Class Period. The Individual Defendants were provided with or had access to copies of the documents alleged herein to be false and/or misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information, the Individual Defendants knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public and that the positive representations that were being made were false and misleading. As a result, each of the Individual Defendants is responsible for the accuracy of Ophthotech's corporate statements and is therefore responsible and liable for the misrepresentations contained therein.

136. However sincerely Defendants may have *hoped* that the Phase 3 Trials would succeed, they acted with scienter by knowingly or recklessly misleading investors about the likelihood of success.

137. Defendants knew, or should have known, that there was a significant risk that the results of the Phase 2b Trial were not indicative of Fovista's efficacy because those results were skewed by the fact that patients in the Lucentis-only group had 17% larger lesions and poorer vision at baseline than patients in the Fovista combination group. Since larger lesions tend to be more chronic, severe, and difficult to treat, and correlate with worse visual acuity, patients in the Fovista combination group – who had smaller lesions and better vision to begin with – were more likely to experience an improvement in visual acuity during the trial, and that improvement was not necessarily attributable to Fovista. Nonetheless, Defendants knowingly or recklessly misrepresented

to investors that the Phase 2b Trial “demonstrated a statistically and clinically significant effect” from Fovista, including a “62% additional benefit over monotherapy,” and characterized the trial as “well conducted” and its “data” as “robust.”

138. Defendants also knowingly or recklessly misled investors about the likelihood that the Phase 3 Trials would succeed by repeatedly emphasizing that the enrollment criteria for the Phase 3 Trials was essentially identical to the Phase 2b Trial, stating, *inter alia*, that:

- Defendants had “made no meaningful changes to the inclusion and exclusion criteria in the[] Phase 3 clinical trials from those we used in our Phase 2b clinical trial.”
- Defendants had “ma[de] all of the aspects of the [Phase 3] trial[s] as close to [the Phase 2b Trial] as possible.”
- Unlike “too many companies [that] make a lot of changes from Phase 2 to Phase 3” and “get surprises,” Defendants had “changed nothing.”
- The Phase 3 Trials were “really similar in virtually every way short of the . . . [end] point of 12 months[.]”
- Defendants’ objective in designing the Phase 3 Trials was to “really not change anything at all” from the Phase 2b Trial.
- “[A]s far as differences between the Phase IIb study and the Phase III, there really aren’t any differences that are material or significant in any way.”
- There were “no changes that we can think of that are significant in any way.”
- “[V]irtually anything that’s material is – has been kept the same.”
- “[R]eally [there] are no material changes.”
- “[I]t’s very important to understand that in none of the [Phase 3] trials at all has there been any changes[.]”
- It was “quite rare to have a Phase 3 be as analogous and almost identical to a Phase 2 as ours is.”
- “[T]his is about as close as you can get, where the Phase 3 is like the Phase 2 . . . it’s remarkable. It’s almost identical.”

139. In truth, Defendants had made a critical change to the enrollment criteria for the Phase 3 Trials by requiring only the presence of SHRM, rather than categorizing patients' lesions by "classic" and "occult" subtypes and then excluding patients with pure occult lesions, as they had done in the Phase 2b Trial. Since SHRM was a newly discovered phenomenon that had not been thoroughly studied and was not fully understood, Defendants had no reasonable basis to state that "the same group of patients" was eligible for inclusion in the Phase 3 Trials as in the Phase 2b Trial. In fact, SHRM can be present in patients whose lesions have either classic or occult components – including patients with pure occult lesions. Therefore, this change to the enrollment criteria meant that the estimated 40% of wet AMD patients with pure occult lesions – who had been excluded from the Phase 2b Trial – were eligible for inclusion in the Phase 3 Trials.

140. This change materially increased the risk that the Phase 3 Trials would fail to replicate the seemingly favorable results of the Phase 2b Trial. Defendants were on notice of this risk because when images of patients' lesions were examined at the end of Ophthotech's phase 1 clinical trial of Fovista, the occult components of the lesions appeared to be unaffected by treatment with Fovista.

141. There is no reasonable dispute that Defendants knew about the lesion size and visual acuity imbalances in the Phase 2b Trial and the changed enrollment criteria for the Phase 3 Trials. Defendants had been in possession of the results of the Phase 2b Trial since 2012, and repeatedly spoke about the results of the trial prior to and during the Class Period, giving rise to a duty to familiarize themselves with the data from the Phase 2b Trial, including patient baseline characteristics. Likewise, Defendants designed the Phase 3 Trials, decided upon the enrollment criteria, and repeatedly spoke about the trials' design and enrollment criteria.

142. Given their medical backgrounds and experience with clinical trials, Defendants understood the significance of the baseline imbalances and the changed enrollment criteria and knew, or recklessly disregarded, that those factors materially increased the risk that the seemingly favorable results of the Phase 2b Trial would not be replicated in the Phase 3 Trials. Nonetheless, Defendants knowingly or recklessly misled investors about the Phase 3 Trials' prospects for success.

143. The fact that Defendants Guyer and Patel ***both sold the majority*** of their personally-held Ophthotech common stock during the Class Period provides strong circumstantial evidence that Guyer and Patel knew that the Phase 3 Trials were far less likely to succeed than they represented to investors. In particular, Defendant Patel – a co-founder of the Company who was ***responsible for the clinical development of Fovista*** – sold **82.2%** of his personally-held Ophthotech common stock during the Class Period for proceeds of approximately **\$22.9 million**. Likewise, Defendant Guyer, Ophthotech's co-founder and CEO, sold **66.3%** of his personally-held Ophthotech common stock during the Class Period for proceeds of approximately **\$22.6 million**.

144. If Guyer and Patel had actually believed their positive statements about the results of the Phase 2b Trial and the Phase 3 Trials' prospects for success in light of the trials' purportedly identical design, it would have been economically irrational for them to sell the majority of their Ophthotech stock, since the value of their shares would have greatly increased following favorable results from the Phase 3 Trials. By selling the majority of their personally-held Ophthotech common stock during the Class Period for proceeds of approximately \$22.6 million and \$22.9 million, respectively, Defendants Guyer and Patel ensured that they would become wealthy even if Fovista failed – an outcome they knew was likely. Shareholders, by contrast, have seen their investments in Ophthotech decimated.

145. Accordingly, Defendants were motivated to engage in this fraudulent course of conduct in order to allow Defendants Guyer and Patel to collectively sell 863,206 shares of their personally-held Ophthotech common stock for proceeds of approximately **\$45.5 million** during the Class Period, as follows:

<u>Insider</u>	<u>Date</u>	<u>Price</u>	<u>Shares Sold</u>	<u>Proceeds</u>	<u>% Sold</u>
Defendant Guyer (CEO, Chairman)	3/2/2015	\$53.82	4,171	\$224,483	
	3/2/2015	\$53.05	14,411	\$764,504	
	3/30/2015	\$48.94	1,800	\$88,092	
	3/30/2015	\$48.19	16,782	\$808,725	
	4/29/2015	\$49.85	340	\$16,949	
	4/29/2015	\$48.13	12,660	\$609,326	
	4/29/2015	\$49.09	5,582	\$274,020	
	5/28/2015	\$47.40	2,400	\$113,760	
	5/28/2015	\$48.64	10,264	\$499,241	
	5/28/2015	\$49.09	5,918	\$290,515	
	6/29/2015	\$50.71	10,581	\$536,563	
	6/29/2015	\$51.51	8,001	\$412,132	
	7/30/2015	\$65.79	5,300	\$348,687	
	7/30/2015	\$66.44	11,488	\$763,263	
	7/30/2015	\$67.15	1,794	\$120,467	
	8/31/2015	\$44.54	10,084	\$449,141	
	8/31/2015	\$45.30	8,498	\$384,959	
	9/29/2015	\$36.37	5,915	\$215,129	
	9/29/2015	\$37.40	3,953	\$147,842	
	9/29/2015	\$38.57	6,180	\$238,363	
	9/29/2015	\$39.11	2,534	\$99,105	
	10/30/2015	\$49.88	18,482	\$921,882	
	10/30/2015	\$50.27	100	\$5,027	
	11/30/2015	\$61.08	2,371	\$144,821	
	11/30/2015	\$62.15	9,135	\$567,740	
	11/30/2015	\$63.23	5,049	\$319,248	
	11/30/2015	\$63.80	2,027	\$129,323	
	12/30/2015	\$78.53	11,631	\$913,382	
	12/30/2015	\$79.31	6,951	\$551,284	
	1/4/2016	\$71.15	862	\$61,331	
	1/4/2016	\$71.93	600	\$43,158	
	1/4/2016	\$72.93	1,121	\$81,755	
	1/4/2016	\$74.05	578	\$42,801	
	1/4/2016	\$74.96	108	\$8,096	
	1/28/2016	\$53.35	14,198	\$757,463	

<u>Insider</u>	<u>Date</u>	<u>Price</u>	<u>Shares Sold</u>	<u>Proceeds</u>	<u>% Sold</u>
	1/28/2016	\$54.10	3,200	\$173,120	
	1/28/2016	\$55.03	600	\$33,018	
	1/28/2016	\$56.29	600	\$33,774	
	3/1/2016	\$44.61	3,000	\$133,830	
	3/1/2016	\$45.53	16,592	\$755,434	
	3/1/2016	\$46.21	2,468	\$114,046	
	4/1/2016	\$41.98	2,110	\$88,578	
	4/1/2016	\$43.21	3,500	\$151,235	
	4/1/2016	\$44.43	12,969	\$576,213	
	4/1/2016	\$45.09	3,481	\$156,958	
	5/2/2016	\$46.01	17,421	\$801,540	
	5/2/2016	\$46.82	4,639	\$217,198	
	6/1/2016	\$52.59	25,766	\$1,355,034	
	6/1/2016	\$53.44	4,294	\$229,471	
	7/1/2016	\$51.13	5,300	\$270,989	
	7/1/2016	\$52.38	17,960	\$940,745	
	7/1/2016	\$52.75	800	\$42,200	
	8/1/2016	\$64.39	21,255	\$1,368,609	
	8/1/2016	\$65.06	2,805	\$182,493	
	9/1/2016	\$52.58	24,060	\$1,265,075	
	10/3/2016	\$44.00	13,828	\$608,432	
	10/3/2016	\$44.77	6,632	\$296,915	
	10/3/2016	\$45.97	1,600	\$73,552	
	11/1/2016	\$34.93	10,530	\$367,813	
	11/1/2016	\$35.93	7,710	\$277,020	
	11/1/2016	\$36.86	<u>3,820</u>	<u>\$140,805</u>	
			438,809	\$22,606,672	66.3%
Defendant Patel (President, Vice Chairman)	4/17/2015	\$50.43	11,300	\$569,859	
	4/17/2015	\$51.09	700	\$35,763	
	5/18/2015	\$51.93	10,700	\$555,651	
	5/18/2015	\$52.19	1,300	\$67,847	
	6/18/2015	\$49.60	8,100	\$401,760	
	6/18/2015	\$50.14	3,900	\$195,546	
	7/20/2015	\$67.26	10,298	\$692,643	
	7/20/2015	\$67.95	11,663	\$792,501	
	7/20/2015	\$68.80	4,954	\$340,835	
	7/20/2015	\$70.19	300	\$21,057	
	8/20/2015	\$47.80	9,630	\$460,314	
	8/20/2015	\$48.96	9,643	\$472,121	
	8/20/2015	\$49.63	7,942	\$394,161	
	9/21/2015	\$45.26	11,601	\$525,061	
	9/21/2015	\$46.14	4,300	\$198,402	

<u>Insider</u>	<u>Date</u>	<u>Price</u>	<u>Shares Sold</u>	<u>Proceeds</u>	<u>% Sold</u>
	9/21/2015	\$47.45	10,814	\$513,124	
	9/21/2015	\$49.24	500	\$24,620	
	10/21/2015	\$42.52	8,300	\$352,916	
	10/21/2015	\$43.27	13,556	\$586,568	
	10/21/2015	\$44.44	5,259	\$233,710	
	10/21/2015	\$45.19	100	\$4,519	
	11/5/2015	\$53.06	12,822	\$680,335	
	11/5/2015	\$53.95	4,200	\$226,590	
	11/5/2015	\$54.80	3,665	\$200,842	
	11/24/2015	\$60.14	19,371	\$1,164,972	
	11/24/2015	\$60.60	7,844	\$475,346	
	12/24/2015	\$76.42	9,100	\$695,422	
	12/24/2015	\$77.32	14,636	\$1,131,656	
	12/24/2015	\$78.20	2,100	\$164,220	
	12/24/2015	\$79.02	200	\$15,804	
	12/29/2015	\$77.00	560	\$43,120	
	12/29/2015	\$77.95	624	\$48,641	
	1/4/2016	\$71.15	677	\$48,169	
	1/4/2016	\$71.93	472	\$33,951	
	1/4/2016	\$72.93	881	\$64,251	
	1/4/2016	\$74.05	454	\$33,619	
	1/4/2016	\$74.96	85	\$6,372	
	1/29/2016	\$53.33	11,418	\$608,922	
	1/29/2016	\$53.92	8,482	\$457,349	
	1/29/2016	\$54.69	100	\$5,469	
	2/29/2016	\$45.04	18,065	\$813,648	
	2/29/2016	\$45.92	1,935	\$88,855	
	3/29/2016	\$40.83	8,603	\$351,260	
	3/29/2016	\$42.05	5,118	\$215,212	
	3/29/2016	\$43.07	6,279	\$270,437	
	4/29/2016	\$46.71	18,435	\$861,099	
	4/29/2016	\$47.78	1,565	\$74,776	
	5/31/2016	\$52.03	1,674	\$87,098	
	5/31/2016	\$53.33	14,317	\$763,526	
	5/31/2016	\$53.81	3,709	\$199,581	
	5/31/2016	\$54.09	300	\$16,227	
	6/29/2016	\$51.37	18,385	\$944,437	
	6/29/2016	\$51.94	1,615	\$83,883	
	6/30/2016	\$50.94	19,146	\$975,297	
	6/30/2016	\$51.86	2,700	\$140,022	
	7/29/2016	\$64.09	15,500	\$993,395	
	7/29/2016	\$64.62	4,500	\$290,790	
	8/29/2016	\$52.80	20,000	\$1,056,000	

<u>Insider</u>	<u>Date</u>	<u>Price</u>	<u>Shares Sold</u>	<u>Proceeds</u>	<u>% Sold</u>
	9/29/2016	\$54.13	7,292	\$394,716	
	9/29/2016	\$54.93	2,612	\$143,477	
	9/29/2016	\$55.75	8,096	\$451,352	
	9/29/2016	\$56.90	2,000	\$113,800	
			424,397	\$22,872,918	82.2%
	Total:		863,206	\$45,479,590	

146. Defendants Guyer and Patel represented that some of these sales were made pursuant to stock trading plans that were adopted in accordance with Rule 10b5-1 of the Exchange Act in an effort to avoid concerns about whether they had material, non-public information when they sold their stock. However, Guyer and Patel's trading plans do not provide a defense to their insider sales because Guyer and Patel adopted and/or amended their trading plans at a time when they were in possession of material, non-public information about the Phase 3 Trials' true prospects for success.

Loss Causation/Economic Loss

147. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Ophthotech common stock and operated as a fraud or deceit on Class Period purchasers of Ophthotech common stock by failing to disclose and misrepresenting the adverse facts detailed herein. When Defendants' prior misrepresentations and fraudulent conduct were disclosed and became apparent to the market, the price of Ophthotech common stock fell precipitously as the prior artificial inflation dissipated. As a result of their purchases of Ophthotech common stock during the Class Period, Plaintiff and the other Class members suffered economic loss, *i.e.*, damages, under the federal securities laws.

148. By failing to disclose to investors the adverse facts detailed herein, Defendants presented a misleading picture of Ophthotech's business and prospects. Defendants' false and misleading statements and omissions had the intended effect and caused Ophthotech common stock

to trade at artificially inflated levels throughout the Class Period, reaching as high as \$78.64 per share on December 29, 2015.

149. On December 12, 2016, before the markets opened, Ophthotech stunned investors when the Company announced the results of the Fovista Phase 3 Lucentis Trials and disclosed that “[n]o benefit [was] observed upon [the] addition of Fovista® to monthly Lucentis® regimen for the treatment of wet [AMD.]” In response to this news, the price of Ophthotech common stock plummeted approximately 86% on more than 30 times the previous day’s trading volume, from a closing price of \$38.77 per share on Friday, December 9, 2016, to close at \$5.29 per share on Monday, December 12, 2016. The price of Ophthotech common stock continued to decline over the next three trading days, closing at \$4.86 per share on December 15, 2016.

150. The precipitous decline in the price of Ophthotech common stock was a direct result of the nature and extent of Defendants’ fraud finally being revealed to investors and the market. The timing and magnitude of the decline in the price of Ophthotech common stock negates any inference that the loss suffered by Plaintiff and the other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to Defendants’ fraudulent conduct. The economic loss, *i.e.*, damages, suffered by Plaintiff and the other Class members was a direct result of Defendants’ fraudulent scheme to artificially inflate the price of Ophthotech common stock and the subsequent significant decline in the value of Ophthotech common stock when Defendants’ prior misrepresentations and other fraudulent conduct were revealed.

CLASS ACTION ALLEGATIONS

151. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all purchasers of the common stock of Ophthotech between March 2, 2015 and December 12, 2016, inclusive, and who were damaged

thereby (the “Class”). Excluded from the Class are Defendants, members of the immediate families of each Defendant, the Company and its officers and directors at all relevant times, any entity in which any excluded party has or had a controlling interest or which is related to or affiliated with any Defendant, and the legal representatives, heirs, successors or assigns of any such excluded party.

152. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Ophthotech common stock was actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds, if not thousands, of members in the proposed Class. In addition, the names and addresses of the Class members can be ascertained from records maintained by Ophthotech or its transfer agent. Notice of the pendency of this action can be provided to such record owners by a combination of published notice and first-class mail, using techniques and a form of notice similar to those customarily used in class actions arising under the federal securities laws.

153. Plaintiff’s claims are typical of the claims of the members of the Class as all members of the Class have been similarly affected by Defendants’ conduct in violation of federal law that is complained of herein. Plaintiff does not have any interests antagonistic to, or in conflict with, the Class.

154. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class action and securities litigation.

155. Common questions of law and fact apply equally to all members of the Class and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to the Class are:

- (a) whether the federal securities laws were violated by Defendants' acts as alleged herein;
- (b) whether Defendants misrepresented and/or omitted material facts about Ophthotech and its business;
- (c) whether Defendants acted knowingly or recklessly in issuing false and misleading statements;
- (d) whether the price of Ophthotech common stock was artificially inflated during the Class Period; and
- (e) to what extent the members of the Class have sustained damages and the proper measure of damages.

156. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it virtually impossible for members of the Class to individually seek redress for the wrongful conduct alleged. Plaintiff knows of no difficulty that will be encountered in the management of this litigation that would preclude its maintenance as a class action.

**Applicability of Presumption of Reliance:
Fraud on the Market Doctrine
and *Affiliated Ute* Doctrine**

157. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud on the market doctrine in that, among other things:

- (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- (b) the omissions and misrepresentations were material;
- (c) the Company's common stock traded in an efficient market;

(d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

(e) Plaintiff and the other members of the Class purchased Ophthotech common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

158. At all relevant times, the market for Ophthotech common stock was efficient for the following reasons, among others:

(a) Ophthotech common stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) as a regulated issuer, Ophthotech filed periodic public reports with the SEC and the NASDAQ;

(c) Ophthotech regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Ophthotech was followed by securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

159. As a result of the foregoing, the market for Ophthotech common stock promptly digested current information regarding Ophthotech from all publicly available sources and reflected such information in the prices of Ophthotech's common stock. Under these circumstances, all purchasers of Ophthotech common stock during the Class Period suffered similar injury through

their purchase of Ophthotech common stock at artificially inflated prices and a presumption of reliance applies.

160. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), because the Class' claims are grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding Ophthotech's business and prospects – information that Defendants were obligated to disclose – positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions.

161. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here, and, therefore, *Affiliated Ute* provides a separate, distinct basis for finding the applicability of a presumption of reliance.

No Safe Harbor

162. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false statements alleged herein. Many of the statements alleged were not identified as “forward-looking” when made, and, to the extent any statements were forward-looking, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Furthermore, to the extent that the statutory safe harbor applies to any forward-looking statements alleged, Defendants are liable for such statements because, at the time they were made, the speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Ophthotech who knew that those statements were false when made.

COUNT I

**Violation of Section 10(b) of the Exchange Act
and Rule 10b-5 Promulgated Thereunder
Against All Defendants**

163. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

164. During the Class Period, Defendants disseminated or approved the materially false and misleading statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

165. Defendants violated Section 10(b) of the Exchange Act [15 U.S.C. §78j(b)], and Rule 10b-5 [17 C.F.R. §240.10b-5], in that they: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's common stock during the Class Period.

166. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Ophthotech common stock. Plaintiff and the Class would not have purchased Ophthotech common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements and/or omissions.

167. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of Ophthotech common stock during the Class Period.

COUNT II

Violation of Section 20(a) of the Exchange Act Against the Individual Defendants

168. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

169. The Individual Defendants acted as controlling persons of Ophthotech within the meaning of Section 20(a) of the Exchange Act, as alleged herein. By virtue of their positions as officers and/or directors of Ophthotech, and their ownership of Ophthotech common stock, the Individual Defendants had the power and authority to cause Ophthotech to engage in the wrongful conduct complained of herein.

170. As set forth above, Ophthotech and the Individual Defendants violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. Moreover, by virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for Ophthotech's §10(b) and Rule 10b-5 violations. As a direct and proximate result of the Individual Defendants' wrongful conduct, Lead Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's common stock during the Class Period. By reason of such conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Determining that this action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, certifying Plaintiff as Class representative, and designating Lead Counsel as Class Counsel;

B. Awarding compensatory damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, together with interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Awarding such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

DATED: June 4, 2018

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& DOWD LLP
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DAVID A. ROSENFELD
ERIN W. BOARDMAN
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Lead Counsel for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on June 4, 2018, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such public filing to all counsel registered to receive such notice.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on June 4, 2018.

/s/ David A. Rosenfeld

DAVID A. ROSENFELD